Original Article

Title

Results of Performance Qualification Testing on Clinically-Used *da Vinci*® *EndoWrist*® Instruments at Hospitals in Germany

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Keywords

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Summary

The purpose of this study is to share the cleaning results of testing clinically used da Vinci Endowrist instruments as performed by hospital personnel in Germany over a 3-year period and to show that better compliance to the manufacturer's instructions and process improvements will increase the cleaning performance results for *EndoWrist* instruments. This testing, in accordance to ISO 15883, serves as the final qualification of the cleaning process described for an instrument by each hospital as part of their quality management system and supports the safe use of the medical device when such processes are followed. Typically, the results of performance qualification testing are not published or available to the general hospital community since these studies only serve to qualify the individual process in place at each institution. These results may serve to help improve the reprocessing practices at hospitals and to provide confidence in the validated reprocessing instructions provided by the manufacturer.

This study presents performance qualification results on clinically used *da Vinci EndoWrist* instruments that were collected during 2012-2014 from 28 hospitals in Germany. In total, 223 instruments were tested after they were used in surgery and then cleaned according to the process described in the procedures in place at each facility. In many cases, the performance qualification test was used to verify the results of staff training, process improvements or as part of an annual process requalification activity. In a few cases, instruments were tested after multiple cycles of clinical use and reprocessing to provide evidence of cleaning efficacy throughout and at the end of the product life. The instruments were evaluated for visual cleanliness and residual protein according to published methods. The data from year to year show a strong trend of improved cleaning results and compliance to the German standards.

The data were also analyzed for special cases in which the effect of staff training, a change in chemical or process parameters and the effect of instrument age showed improvements in or a continuation of acceptable cleaning performance. These results validate the manufacturer's approved reprocessing instructions (in the locations where these instructions were followed) and the design of da Vinci instruments for cleanability and hygienic use.

Materials and Methods

As part of the performance qualification process described in ISO 15883 [1] and in accordance with guidance from local regulatory authorities, the hospital central sterile supply departments (CSSD) in this study evaluated the efficacy of their procedures for reprocessing *da Vinci* 8mm *EndoWrist* instruments. CSSD staff first performed the initial cleaning and sterilization of the instruments required before first clinical use. In some cases, the instruments were reprocessed twice prior to the first clinical use according to the recommendations of the AG *da Vinci* Working Group to remove any residual substances that might give false positive signals in the *o*-phthalaldehyde (OPA) protein test [2]. This double reprocessing is only recommended when the instrument will be evaluated for residual protein after one clinical use, otherwise this additional cleaning cycle is not required.

The instruments were then used in a surgical procedure and thereafter reprocessed according to the validated reprocessing instructions provided by Intuitive Surgical or in accordance with the internal procedures of the hospital. According to hospital procedure and the recommendations of either the local regulatory authorities or a professional hygiene institute, *da Vinci EndoWrist* instruments in this study were sent to a testing laboratory (usually in cold packaging) for visual examination and protein testing after different numbers of surgical uses ranging from 1 surgical use to 10 (representing the device end of life). In some cases, the number of surgical uses on the instrument is not known. These instruments were tested, but not returned to the hospital for further clinical use. At a few hospitals, cleaning evaluation testing was performed at the laboratory on the same set of instruments after the first, fifth and tenth surgical use to demonstrate repeated cleanliness and to show that soil does not accumulate from use to use. In all cases during the reprocessing prior to residual protein testing, the washer disinfector cycle was aborted prior to thermal disinfection and steam sterilization was not performed to prevent the fixation of protein on the device that occurs at high temperatures. When instruments were returned to the hospital for further clinical use after protein extraction (during 1, 5, 10 testing), the hospitals followed their reprocessing and sterilization procedures to prepare the instruments for subsequent use. This was done in accordance with the guidance provided by the certified hygiene laboratory which was overseeing the process qualification.

The cleaning evaluation testing on *EndoWrist* instruments was performed by either a destructive or a non-destructive method as described by the AG *da Vinci* Working Group [3] or by the validated methods used by each hygiene institute. In some cases, instruments evaluated using the non-destructive method were returned to the hospital for further clinical use and reprocessing and then sent back to the hygiene institute for repeated testing. The use of the

destructive test method allows for the visual examination of the internal components of the instruments.

Unlike simple or laparoscopic surgical devices that are exposed fully to soil within the surgical field during use, *EndoWrist* instruments have distinct regions of the device that are either in direct patient contact, indirect patient contact or patient non-contact regions, based on the design and use of the instrument during surgery. The internal surfaces of the housing of the 8mm *EndoWrist* Si instruments are >26cm from the tip of the instrument. Even under insufflation pressure used during a surgery, only a small amount of soil from the patient can travel a limited distance up the shaft during use. Unlike other minimally-invasive instruments with tight internal tolerances, the inside of the shaft of the 8mm *EndoWrist* instruments is qiute open. Consequently, surgical soil can travel up the shaft by gravity, but not by wicking forces. The regions of the instrument are shown in Figure 1.

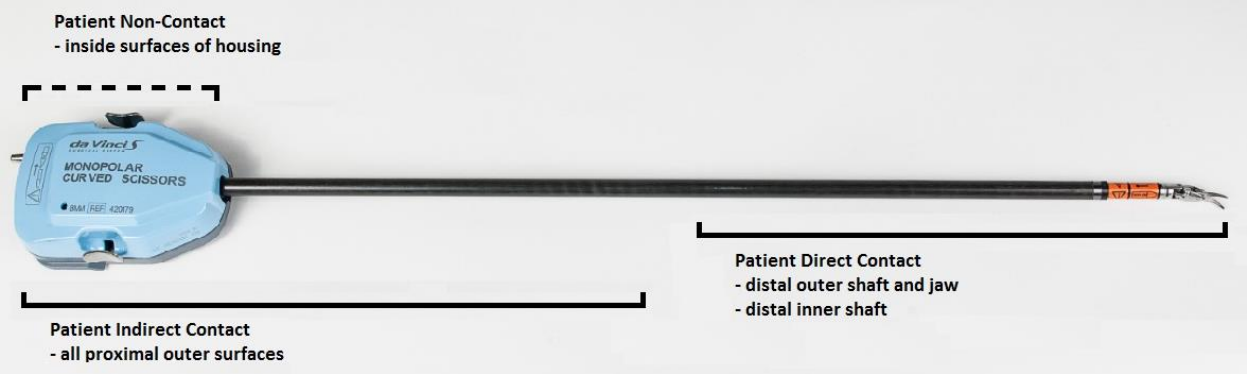

Figure 1. Picture of an *EndoWrist* instrument showing the different regions of the instrument divided into direct patient contact, indirect patient contact and the patient non-contact regions.

Residual protein was extracted from both the tip and the inner shaft of the instruments by elution using 1% sodium dodecyl sulfate (SDS) aqueous solution [3]. The tip was extracted by immersing it in 4ml of 1% SDS solution in a narrow test tube and then soaking and agitating the tip in the extract repeatedly using a vortex mixer over a period of 30 minutes. The shaft was extracted by injecting 6ml of 1% SDS solution into the primary flush port (flush port #1) and by soaking and agitating the mixture within the shaft by pumping the extract up and down the shaft repeatedly using the syringe over a period of 30 minutes. The extract was then withdrawn from the shaft using the syringe [3]. During destructive instrument testing, the tip of the instrument was separated from the shaft by cutting the hypotube cables. The severed tip was extracted as indicated above. During destructive testing of the shaft, the shaft and its internal components (the cables and flush tube) were extracted by adding a water-tight cap on one end of the shaft, injecting 6mL within the shaft and capping the other end. Agitation of the mixture was performed by tilting the ends of the shaft up and down repeatedly over a period of 30 minutes [3]. One of the certified hygiene laboratories involved in testing the *EndoWrist* instruments in this study uses a method for destructive testing which varyies slightly from the

method described above. This method is internally validated by the laboratory, but not described because of its proprietary nature.

The eluates were then tested for residual protein using either the OPA [4] or the bicinchoninic acid (BCA) protein test methods using a spectrophotometer.

The test results presented in this study were collected from March, 2012 to September, 2014. Summary statistical analyses were performed on the results from 2012 to 2014, however a detailed analysis of the data is presented on the results form 2013-2014, during which time the manufacturer performed training in hospital CSSD's on the validated reprocessing method described in the manufacturer's reprocessing instructions. Prior to this training, the level of compliance to the validated reprocessing instructions provided by the manufacturer was highly variable in many of the hospitals, and consequently, the results of residual protein testing were very inconsistent during this time. The larger sets of data summarized in tables 2 and 3 also contain a statistical analysis (*p*) of the difference in the populations of results. The *p*-value in these tables is based on an analysis of the median of the populations of data instead of the mean. This was done because the data in each population are skewed (not normally distributed) because of the few high values >100µg that exist in each data set. Basing the p-value calculation on the median is the more appropriate and conservative statistical approach for non-normal populations.

Results

During the period from 2012 to 2014, performance qualification testing results were generated by two hygiene institutes in Germany as well as other data reported by individual hospital CSSD departments which was conducted at the hospital site by professional validators. 223 results were collected from 28 hospitals over the three years. Information on the *EndoWrist* instrument type being tested and the washer disinfector and cleaner used during validation were not collected during 2012, consequently, a detailed analysis is not performed on these results. For the purpose of confidentiality, the hospitals in this study are identified by an assigned number.

Four instrument data points from the 2013 results are excluded from the analysis for the following reasons. Two of the instruments from Hospital #27 were received by the testing laboratory with visible soil on the jaws of the instruments and were not tested for residual protein since they failed the visual examination. Additionally, two instruments from Hospital #12 were extracted with 1% SDS at the testing laboratory and the extracts were found to be visibly turbid. According to the procedures of the laboratory, further testing is not conducted on turbid samples. The reason for the turbidity in these extracts was not determined, however, turbidity or cloudiness in the extracts can be caused by the application of excessive surgical lubricant or incomplete removal of surgical lubricant during reprocessing. Turbidity in the sample can invalidate the results of a spectrophotometric analysis since the light scattering caused by turbidity in the sample cannot reliably be distinguished from light absorbance that is proportional to the protein reaction.

The following table (Table 1.) shows the types and numbers of instruments that were tested. These instruments represent the more commonly used types in da Vinci robotic procedures. The monopolar and bipolar cautery instruments also represent the most difficult to clean instruments because of the charring of blood and tissue that occurs on the jaw of the instruments during electrocautery. 61 of the 81 unknown instruments types are from the 2012 testing results.

Table 1. Summary of the *EndoWrist* instrument types used in the performance qualification testing.

Number of Instrument Types Tested,
2012-2014 Data

n	**Instrument Type**
Bipolar Cautery Instruments	
7	Fenestrated Bipolar Forceps
20	Maryland Bipolar Forceps
4	PK® Dissecting Forceps
Monopolar Cautery Instruments	
36	Monopolar Curved Scissors
1	Permanent Cautery Hook
Non-Energized Forceps	
4	DeBakey Forceps
26	ProGrasp™ Forceps
Needle Drivers	
41	Large Needle Driver
3	Mega™ SutureCut™ Needle Driver
Other – Unknown	
81	Unknown Instrument Type
223	**Total**

Among the 28 hospitals where performance qualification testing data were available, hospitals tested between 1 and 16 instruments during the 3 year time period. The average number of instruments tested at each hospital is 7.9 instruments with a standard deviation of 4.5 instruments. The testing frequency was broadly distributed and the results are not dominated by one or a few hospitals. It should also be noted that several of the hospitals conducted repeat testing during this time as part of their plan to improve cleaning performance through

staff training, process improvements or to document the results of repeat testing throughout the use life of the instruments.

An overall statistical summary of all the results from 2012-2014 is found in Table 2 which shows the number of results, the average and standard deviation for each year. All of the residual protein results presented in this study are the combined results of both the instrument tip and shaft extracts and are presented as total residual protein in micrograms (µg). Table 2 also shows the number of results <100 µg, between 100 and 199µg of residual protein, the number of results that exceed 200µg and the *p*-value demonstrating that the data from each of the 3 years are significantly different from one another. These ranges of residual protein correspond to the "Alarm value" (from >100 to ≤200µg) and "Limit value" (>200µg) described in the guideline compiled by the DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning [5] which were in effect at the time these data were collected. We have also listed the number of values which are < 100µg which corresponds to the residual protein limits listed by the KRINKO/BfArM guideline [7]. These values in the guideline represent the important decision points for hospitals when validating the performance of their reprocessing process through the performance qualification study. Results in the Alarm value range allow the CSSD to continue reprocessing operations while identifying, implementing and revalidating measures to improve the process. When results are found that exceed the Limit value, hospitals discontinue reprocessing operations while the performance is optimized.

Table 2. Statistical summary of the data collected from performance qualification testing on *EndoWrist* instruments at 28 hospitals within Germany from 2012 to 2014. The last 2 columns indicate the number of results between 100 and 199 µg of residual protein and the number of results that exceed 200 µg.

Summary Statistics of Performance Qualification Testing at 28 Hospitals

		Total Protein (µg)		Number			
Year	*n*	Ave	SD	<100µg	100-199µg	≥200µg	*p* [1]
2012	61	176.3	115.4	19	21	21	
2013	89	72.7	82.4	73	13	3	<0.0001
2014	73	35.1	34.5	70	2	1	
Total	223						

[1] *p* value based on a comparison of the medians

The summary statistics show an improvement from year to year in the average and standard deviation of the residual protein results as well as a significant reduction in the number of results that exceed the threshold limits. The p-value as calculated by the Kruskal-Wallis test indicates that all 3 populations of data are statistically different.

Figure 2 shows a graphical representation of the results from 2013-2014 by hospital. 23 hospitals are represented in these results. The distribution of results at each site is an indication

of the performance of their process and the level of compliance to the reprocessing instructions provided by the manufacturer. In some cases, the data represent repeated testing conducted as part of the hospital's efforts to make process improvements.

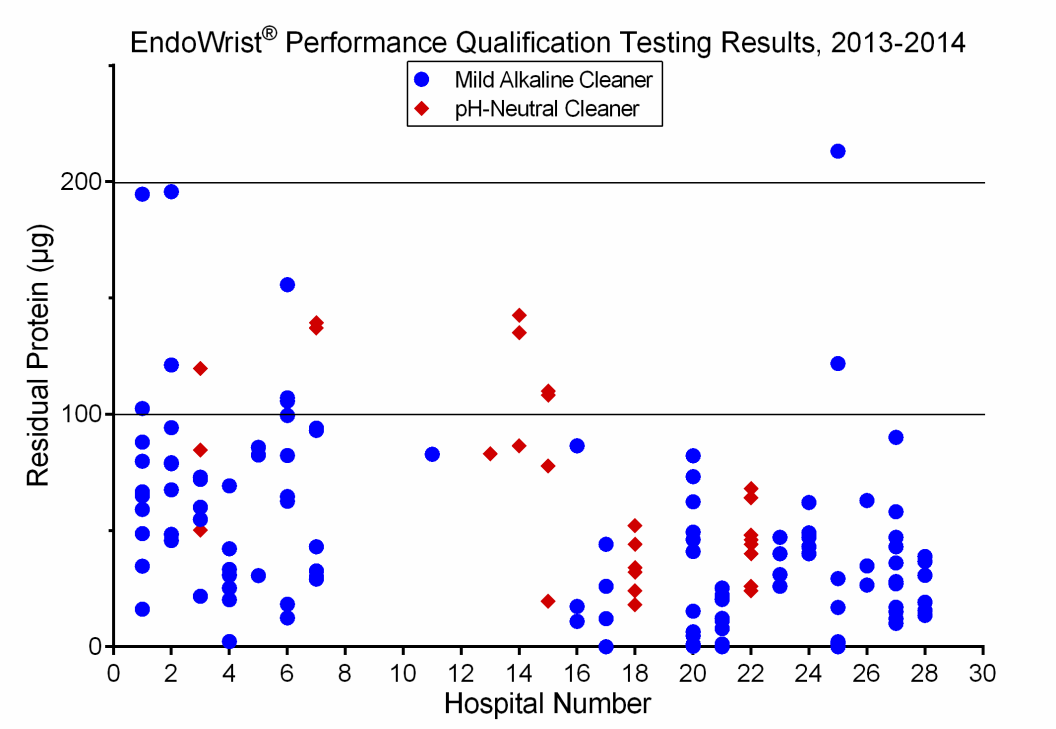

Figure 2. Distribution of the performance qualification testing results from 23 hospitals in Germany from 2013-2014. Three of the 159 test results are not shown in this graph (all from 2013). The three results in question are greater than the average for the year plus 2 standard deviations which indicate that these may be outlier results. These results, 427µg (hospital #3), 523 µg (hospital #6) and 332 µg (from hospital #7) are excluded from this graph only to ease interpretation of the remaining results. All three of the outlier results are included in the statistical summaries below. The results of process improvements for the hospitals #3, #6 and #7 in Case Studies 1 and 2 are given below.

Table 3 shows a more detailed comparison of the cleaning results when mild alkaline or pH-neutral cleaners are used. In general, mild alkaline cleaners produce superior cleaning results when used as part of the validated process. The manufacturer's instructions include the use of an enzymatic cleaner in two separate steps in the cleaning process: 1) in the soaking step of the pre-cleaning process and also 2) in the automated washer disinfector. A more detailed examination of the results from the use of pH-neutral cleaners shows that not all pH-neutral cleaners show the same trend for higher results. These results highlight the importance of considering each part of the cleaning process in the performance qualification for *EndoWrist* instruments including an evaluation of the efficacy of the cleaners used.

Table 3. Statistical summary of the performance qualification results divided by cleaner type.

Summary of Differences Between pH-Neutral and Mild Alkaline Cleaners, 2013-2014 Result

		Total Protein (µg)		Number			
Cleaner Class	*n*	Ave	SD	<100µg	100-199µg	≥200µg	*p* [1]
pH-Neutral	31	85.9	88.6	22	7	2 (6.5%)	<0.0016
Mild Alkaline	124	48.2	59.7	114	8	2 (1.6%)	

pH-Neutral	n	Ave	SD	<100µg	100-199µg	≥200µg	*p* [1]
Brand A	15	136.8	105.8	6	7	2	<0.0001
Brand B	16	38.3	15.0	16	0	0	

[1] *p* value based on a comparison of the medians

The results from the 2013-2014 testing were further analyzed to highlight special cases where training of the CSSD staff to the manufacturers reprocessing instructions and changes to the reprocessing parameters for *EndoWrist* instruments demonstrated improvement in the results of the performance qualification. Additionally, a few hospitals conducted repeat testing on the same set of *EndoWrist* instruments to show that visible biological soil does not accumulate on the distal tip and the distal inner shaft of the instrument with repeated use.

Case Study 1 – Improved Cleaning Process and Staff Training

9 of the 23 hospitals performed repeated testing during 2013-2014. In some cases repeat testing was performed as part of annual requalification activities and in other cases repeat testing was performed to confirm the effect of staff retraining and/or cleaning process improvements. Examples of these data are summarized in Tables 4 and 5.

Table 4 shows the results of repeat testing at 5 hospitals where a significant improvement in cleaning performance was demonstrated after process improvements were made and/or staff retraining was conducted. This improvement is most significantly seen in the reduction in total residual protein results that exceed 100µg. Three other hospitals performed repeated testing (excluding the 2 cases summarized in Table 5.). Thesehe results showed consistent cleaning performance in both rounds of testing and no residual protein values >100µg.

Table 4. Results of performance qualification testing before and after staff retraining and process improvements.

Performance Improvements After Staff Training

		Protein Test 1 (µg) (before training)			Protein Test 2 (µg) (after training)		
Hospital #	*n*	Ave	SD	>100µg	Ave	SD	>100µg
1	10	87.2	60.2	2/6	57.4	19.8	0
2	8	101.7	59.3	2/5	73.9	23.4	0
6	10	149.6	170.1	3/7	61.3	47.4	1[3]/3
27	13	58.0	NA[1]	2[2]/3	32.5	24.0	0

[1]only 1 instrument tested, [2]instruments with visible soil on the tip, [3]107µg result

This repeated testing after retraining and/or process improvements shows reductions (calculated by subtracting the values from protein test 2 from protein test 1) in the average residual protein ranging from -11.6µg to -88.3µg and a reduction in the standard deviations ranging from -0.3µg to -122.7µg. Hospital 6 saw the most improvement in cleaning results with an -88.3µg reduction in the average and a -133.7µg reduction in the standard deviation. The large reduction in both average and standard deviation seen in repeated testing at hospital 6 is partly due to the influence of the outlier value (523µg) observed during the first testing results. All the results of repeated testing, with one exception (107µg at Hospital 6) showed results below 100µg after staff retraining and cleaning process improvements.

Case Study 2 – Change from pH-Neutral to Mildly Alkaline Cleaner

At two hospitals, a change in the process was made which included a switch from a pH-neutral to a mildly alkaline enzymatic cleaner used in the washer disinfector. Table 5 shows the results of the performance qualification before and after the change in cleaner. The results after the process change show a reduction in residual protein and an elimination in the number of residual protein results that exceed 100µg.

Table 5. Results of performance qualification testing before and after switching from a pH-neutral to a mildly alkaline cleaner used in the washer disinfector.

Performance Improvements After a Change in Cleaner

		Protein Test 1 (µg) (pH-neutral)			Protein Test 2 (µg) (mild-alkaline)		
Hospital #	*n*	Ave	SD	>100µg	Ave	SD	>100µg
3	9	170.4	173.4	2/4	56.2	20.8	0
7	9	202.8	111.9	3/3	53.6	31.3	0

This repeated testing after the change from a pH-neutral to a mildly alkaline cleaner shows a reduction in the average residual protein results ranging from -114.2µg to -149.2µg and reductions in the standard deviation ranging from -80.6µg to -152.6µg. Both hospitals saw an improvement in cleaning results with this change. For both Hospitals 3 and 7, pH-neutral cleaner Brand A (see Table 3) was the product that was replaced by the mildly alkaline chemical. All the results of repeated testing were below 100µg after the change in cleaner.

Case Study 3 – Repeated Testing Throughout Use Life

At the recommendation of the hygiene institute conducting the cleaning validation, three hospitals chose to conduct a form of repeated testing in which the same set of 4 instruments (each a different instrument type) were evaluated visually and tested for residual protein using a non-destructive method after the first and fifth clinical use. After the tenth clinical use (representing the end of life), the instruments were evaluated and tested using the destructive test method [3]. As with the other testing, in order to avoid the fixation of residual protein the washer disinfector cycle was aborted prior to thermal disinfection and steam sterilization was not performed. The instruments were shipped to the hygiene laboratory in cold packaging, to prevent the growth of bacteria and then evaluated visually and for residual protein. After testing, the instruments were sent back to the hospital and used in additional surgical procedures. After the 10th clinical use, the instruments were reprocessed as described and sent to the hygiene laboratory for destructive testing that included visual examination of both external and internal components and residual protein testing. Table 6. shows the results of this type of repeated testing.

Table 6. Results of residual protein testing on instruments after the 1st, 5th and 10th clinical uses.

Results of 1, 5, 10 Use Testing

		Residual Protein Test Results (µg)						
		After 1st Use		After 5th Use		After 10th Use		
Hospital #	*n*	Ave	SD	Ave	SD	Ave	SD	>100µg
17	11	<LOD[1]		<LOD[1]		27.3	16.0	0
20	12	31.1	29.0	5.3	6.9	60.6	20.1	0
21	12	<LOD[1]		13.7	9.6	16.4	7.9	0
Total	35							

[1]below the limit of detection for the protein test method

In two hospitals (#17 and #21), the results after one clinical use were below the limit of detection for the protein test in use at the hygiene laboratory; hospital #17 showed the same results after the 5th clinical use. As part of the protein test method validation, each laboratory establishes a limit of detection which represents the lowest value that can be distinguished from zero. Consequently, any result below the limit of detection is considered to be equivalent

to “not detectable”. The 1, 5, 10-use testing at these hospitals show very low residual protein results which indicate that surgical soil does not accumulate on or in the instruments with use. It should be noted that the destructive test method used after the 10th clinical use may produce material fragments. These fragments may interfere with the spectrophotometric test methods used to assess residual protein as these depend on light transmission through the extract. The 10th-use testing at hospital #17 was performed on a different set of instruments. All of the instruments evaluated from these 3 hospitals after the 1st, 5th and 10th clinical uses showed no evidence of visual soil, either in the non-destructive tests (after the 1st and 5th use) or in the destructive test (after the 10th use).

Discussion and Conclusions

The manufacturer provides reprocessing instructions which are formulated in accordance with ISO 17664 [6] and provides training and support for the reprocessing staff. The validated automated cleaning method requires manual pre-cleaning steps followed by processing in an automated washer disinfector. A manual process is also validated, which requires the use of an ultrasonic bath. For both the manual and automated processes, precleaning steps are described in the manufacturer’s reprocessing instructions. A flowchart describing a high-level overview of the validated automated cleaning method (including the precleaning steps) for *EndoWrist* instruments is shown in Figure 3.

Outline of the Automated Cleaning Process, Including Pre-cleaning Steps

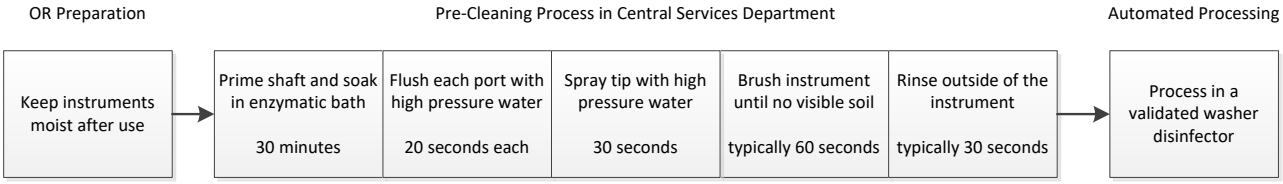

Figure 3. Flowchart showing the main steps of the *da Vinci* S and Si 8mm *EndoWrist* instrument automated cleaning process, including the pre-cleaning steps.

It is important to note that hospital CSSDs may develop internal procedures for the reprocessing of surgical devices that differ from the manufacturer’s instructions as long as these procedures are validated by professionals. Local factors may influence the outcome of performance qualification results, such as water quality used in reprocessing, appropriateness of tools (ie. brushes) available for use, the level of training of CSSD staff and their compliance to the manufacturer’s or hospital’s procedure. The hospital procedures for the transport and storage of instruments prior to the start of reprocessing will also influence the ease of cleaning of the devices since long transport time leads to additional drying of the surgical soil. Consequently, it is important for each hospital to evaluate the cleaning performance of the process approved for use at their location. There is some variation in the results from individual hospitals in this study which reflects this variation in local processes.

With the exception of the 2 instruments discussed in the data exclusion section, all instruments passed visual examinations for protein residue. Even after destructive testing, no surgical soil was found on the internal surfaces of the instruments.

While mildly alkaline cleaners show better cleaning results in general, one of the two pH-neutral cleaners used at hospitals in this study showed consistently acceptable cleaning results. The efficacy of cleaner used in a washer disinfector is dependent on the WD cycle times and other factors. For example, contact time may be increased to allow more time for enzymes to have their effect in hydrolyzing residual protein. Therefore, it should not be concluded that pH-neutral cleaners are not capable of producing cleaning results in compliance with local standards.

In conclusion, over a three-year period, 223 *da Vinci* 8mm *EndoWrist* instruments were used in clinical cases at 28 hospitals in Germany, then evaluated for residual protein as part of performance qualification testing according to ISO 15883-1. Despite the variation at each hospital site, these data show that acceptable cleaning results are achieved with *da Vinci EndoWrist* instruments in accordance with local standards established for Germany [7]. A further study of special cases shows that training of CSSD staff on the manufacturer's reprocessing instructions and improvements made to the cleaning process produce improved results. In a few cases, a special method of testing was performed to evaluate instruments repeatedly throughout their use life. These results of 1, 5 and 10-use testing in combination with the result of visual inspection for all tested instruments demonstrate that EndoWrist instruments do not accumulate soil during their rated use lives.

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