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FINAL REPORT

Confidential and Proprietary

Study No. 1803-164 Revision A

MECHANICAL CLEANING VALIDATION OF THE DEMAYO KNEE POSITIONER BASE W/ 903 SINGLE LEVER CLAMP PROTEIN ANALYSIS

Prepared for:

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Date

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Innovative Medical Products
Mechanical Cleaning Validation of the DeMayo Knee Positioner Base w/ 903 Single Lever Clamp – Protein Analysis

Study No.:	1803-164 Revision A
Sponsor:	Innovative Medical Products 87 Spring Lane Plainville, CT 06062
Study Director:	Corey Centerwall – Study Director
Report Prepared By:	Kimberly Miller – Laboratory Technician
Study Personnel:	Kimberly Miller – Laboratory Technician
Test Objective:	To validate the mechanical cleaning process of the DeMayo Knee Positioner Base w/ 903 Single Lever Clamp.
Test Sample:	DeMayo Knee Positioner Base w/ 903 Single Lever Clamp: See Bill of Materials, Table 1.

References:

1. AAMI TIR12:2010 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities. A Guide for Device Manufacturers 1st Ed.
2. AAMI TIR30:2011 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices.
3. Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient used flexible endoscopes before and after cleaning. *Am J Infect Control* 1999; 27:392-401.
4. Alfa MJ, Olson N, Degagne P, Jackson M. A survey of reprocessing methods, residual viable bioburden and soil levels in patient-ready endoscopic retrograde choliangiopancreatography duodenoscopes used in Canadian Centers. *Infect Control Hosp Epidemiol, 2002, vol. 23, pp. 198-206.*
5. Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff. March 17, 2015
6. Study No. 1101-19 Process Validation of the Protein Analysis Procedure
7. Micro BCA Protein Assay Kit Instructions
8. HIGHPOWER Validation Testing & Lab Services Internal Standard Operating Procedures
9. Innovative Medical Products DeMayo Knee Positioners Instructions for Use

1.0 INTRODUCTION:

This report details the methods used to verify the effectiveness of the manufacturer's mechanical cleaning procedure for the DeMayo Knee Positioner Base w/ 903 Single Lever Clamp. The devices were inoculated with an artificial test soil in various areas including those considered to be the most challenging to clean and most likely to be soiled during actual use. The devices then were processed in accordance with the cleaning procedure delineated in Section 5.0 using a washer/disinfector with validated cycle parameters that is legally marketed in the US. The devices were assayed and any residual protein was recovered to determine if adequate cleaning was achieved. This testing was repeated for five (5) simulation cycles followed by three (3) efficacy cycles.

2.0 JUSTIFICATION:

This test method was chosen by the sponsor and was based on methods outlined in AAMI TIR30:2011. Cleaning instructions for reusable medical devices require validation in order to assure proper and safe reprocessing of the devices by health care facilities. It is well known that a device which has not been cleaned properly may inhibit the ability of the sterilization process to achieve the proper sterility assurance level. This cleaning procedure must be able to remove gross amounts of soil from the test device in order for it to be determined clean and safe for further processing. This study verified that gross amounts of soil can be removed from the devices following the recommended cleaning procedure.

Worst case cleaning conditions were used throughout the validation. For example, cleaning solutions were prepared according to the manufacturer's instructions using the lowest range of concentration recommended (minimum effective concentration). The least effective (lowest) cleaning temperatures, within recommendations, were used for the rinsing and cleaning steps.

The artificial test soil used to inoculate the devices simulated worst case contaminants (body fluid/tissue) that may come in contact with the device and remain on the devices after clinical use. The devices were soiled using the artificial test soil and inoculated in the most difficult to clean locations and areas most likely to be soiled during actual use. These procedures provided worst case soiling conditions for the cleaning validation. The surface area of the device was used during testing to perform calculations to determine soiling levels for the devices.

Acceptance criteria was based on study data of residual protein levels of properly cleaned medical instruments which indicated that the level of protein after cleaning was less than 6.4 $\mu g/cm^2$ (Alfa et al., 2002). A protein level of less than 6.4 $\mu g/cm^2$ on the device after performing the recommended cleaning procedure indicated adequate cleaning and demonstrated that the cleaning method was efficacious in removing soil.

3.0 EQUIPMENT AND MATERIALS:

3.1 DeMayo Knee Positioner Base w/ 903 Single Lever Clamp: See Bill of Materials, Table 1.
3.2 Heparinized rabbit blood, Valley Biomedical: Lot # 8G1353
3.3 Saline, RICCA: Lot # 2607A36
3.4 Fetal bovine serum, Gibco Life Technologies: Lot # 1865222
3.5 Dry milk powder, Difco: Lot # 7114758
3.6 Protamine sulfate, Gibco: Lot # SLBG6301V
3.7 Tri-Power Enzymatic Cleaner, United Biotech: Lot # 18-2315D
3.8 Steris Renu-Klenz Neutral pH Cleaner: Lot # 292957
3.9 Extraction fluid, deionized water
  3.9.1. Deionizing unit: Equipment # 680
  3.9.2. Resin Tank: Lot # MB-115-062718

3.10 Extraction container, Uline 8mil polybag, 36" x 48": Reference #S-14430
3.11 Mechanical washer, Steris Amsco Reliance 444: Equipment # 504
3.12 Spectrophotometer, Genesys 30: Equipment # 734
3.13 Micro BCA Protein Assay Kit, Thermo Scientific: Lot # TD263832
3.14 NIST traceable timer: Equipment # 739
3.15 Temperature sensors: Equipment # 694, 740
3.16 Lint-free cloths, Cleveland Cotton Products: Catalog # 306-50

4.0 PREPARATION OF ARTIFICIAL TEST SOIL:

The artificial test soil contained the following components:

2.5 ml heparinized rabbit blood
2.5 ml saline
5.0 ml fetal bovine serum
3.0 g dry milk powder

Note: Protamine sulfate was added before inoculation to initiate coagulation.

5.0 PROCEDURE:

5.1 The devices from Table 1 were obtained. See Table 2 for testing sample sizes.
5.2 Prior to testing, all test samples, positive, and negative controls were pre-cleaned following steps 5.5-5.9. Devices were disassembled for cleaning.
5.3 The test samples were assembled per IMP DeMayo Knee Positioner Instructions for Use and inoculated in the most difficult to clean locations and areas most likely to be soiled during actual use with the prepared artificial test soil per the device soiling description and Figures 1 and 2.
5.4 The inoculated test samples were allowed to dry at room temperature for a minimum of two (2) hours to simulate worst case conditions.
5.5 A cleaning solution using Tri-Power Enzymatic Cleaner was prepared according to the manufacturer's instructions using the minimum effective concentration (1/8 oz. per gallon) and warm tap water.
5.6 The disassembled test samples were disassembled and allowed to soak in enzymatic cleaner for a minimum of fifteen (15) minutes.
5.7 The test samples were loaded into the mechanical washer soiled face up (i.e. baseplate with the carriage side up.) The test samples were mechanically cleaned per the parameters listed in Table 3.
5.8 The test samples were thoroughly dried with soft, lint-free cloths.
5.9 The test samples were visually inspected for remaining soil. Throughout all soiling cycles, no visible soil was observed.
5.10 Steps 5.3 through 5.9 were repeated four (4) more times for a total of five (5) repetitive inoculating and cleaning cycles to simulate soil accumulation that might occur during actual use.
5.11 Each test sample was placed in a separate extraction container with extraction fluid. Each extraction container was manually shaken/ agitated for five (5) minutes.
5.12 Steps 5.3-5.9 and 5.11 were repeated two (2) times for a total of three (3) efficacy cycles.
5.13 For the negative control, steps 5.5-5.9 and 5.11 were repeated on an unsoiled sample.
5.14 For the positive control, steps 5.3-5.4 were repeated. The positive control was extracted per step 5.11. A method of exhaustive extraction was performed on the positive control to remove any residual soil on the device. A correction factor was calculated using the exhaustive extraction of the positive control and applied to the tests samples and negative control.

5.15 Following the Micro BCA protein assay kit manufacturer's instructions, the protein assay kit was used to determine the protein concentration ($\mu g/cm^2$) for each of the devices.

5.16 All results were recorded. See Table 4.

6.0 RESULTS:

6.1 Each test sample showed a protein level of less than 6.4 $\mu g/cm^2$ after cleaning.

6.2 Each test sample was free of visible soil after cleaning.

7.0 DISCUSSION:

7.1 In order to soak the devices in step 5.6, the boot and clamp were separated from the knee positioner.

7.2 Per sponsor request, the Prolystica 2X Concentrate Enzymatic and Neutral detergents were replaced with Tri-Power Enzymatic Cleaner and Renu-Klenz Neutral pH Detergent. Items 3.7 and 3.8 of the Equipment and Materials section were updated to reflect this deviation and Table 3.

7.3 Table 3 was updated to reflect:

7.3.1 Thermal rinse cycle increased from one (1) to five (5) minutes per ISO 15883 requirements for the duration of a mechanical thermal rinse cycle. This change was client approved.

7.3.2 Worst case concentrations of the "enzyme wash cycle" and the "Wash I" cycles were updated from 1/8 oz. per gallon to 1/4 oz. per gallon which is the minimum programmable concentration for the Steris Amsco Reliance 444 mechanical washer.

8.0 CONCLUSION:

The study results validate that the manufacturer's mechanical cleaning instructions are efficacious for removing gross amounts of soil from the DeMayo Knee Positioner Base w/ 903 Single Lever Clamp to a protein level of less than 6.4 $\mu g/cm^2$ per device.

BILL OF MATERIALS:

Part Number	Description	Quantity	Surface Area (cm^2)
860-793-0391	DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	5	5205.66

TABLE 1

TESTING SAMPLE SIZES

Cycle	Test Samples	Negative Controls	Positive Controls
Simulated Use 1	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	NA	NA
Simulated Use 2	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	NA	NA
Simulated Use 3	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	NA	NA
Simulated Use 4	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	NA	NA
Simulated Use 5	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	NA	NA
Efficacy 1	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	1: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	1: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp
Efficacy 2	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp		
Efficacy 3	3: DeMayo Knee Positioner Base w/ 903 Single Lever Clamp		

TABLE 2

MECHANICAL WASHER CYCLE PARAMETERS

Treatment	Time (mm:ss)	Temperature	Cleaning Solution
Pre-wash	10:00	Cold tap water	N/A
Enzyme Wash	5:00	Hot tap water	Enzyme detergent: Tri-Power Enzymatic Cleaner 1/4 oz. per gallon
Wash I	10:00	65°C	Neutral detergent: Renu-Klenz Neutral pH Cleaner 1/4 oz. per gallon
Rinse	:15	Hot tap water	N/A
Thermal Rinse	5:00	93°C	N/A
Dry	30:00	110°C	N/A

TABLE 3

DEVICE AND SOILING DESCRIPTIONS

DEMAYO KNEE POSITIONER BASE W/ 903 SINGLE LEVER CLAMP

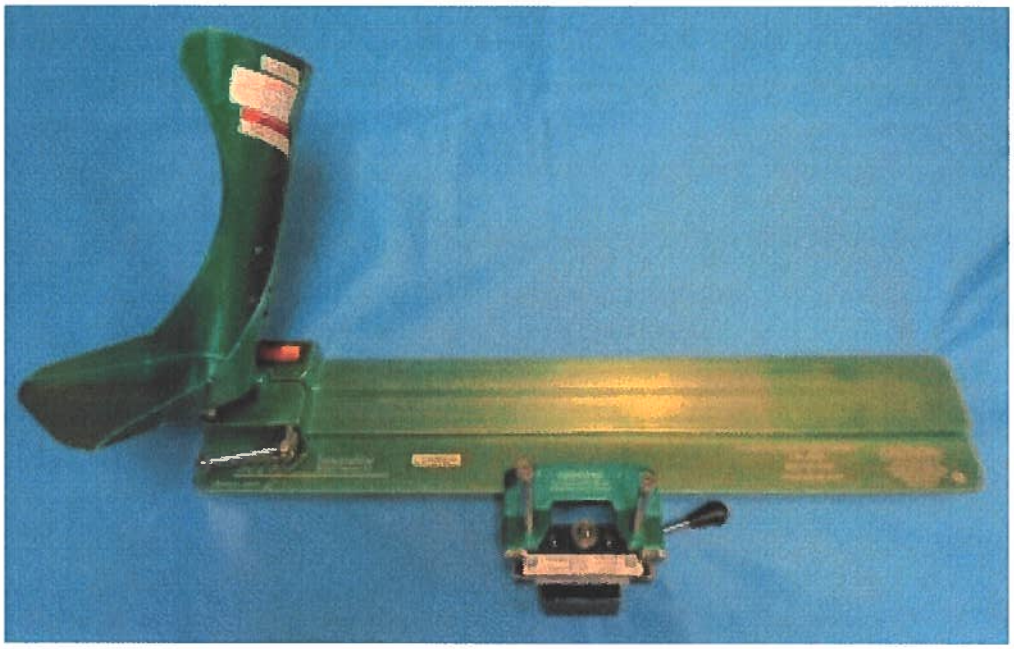

FIGURE 1

903 SINGLE LEVER CLAMP

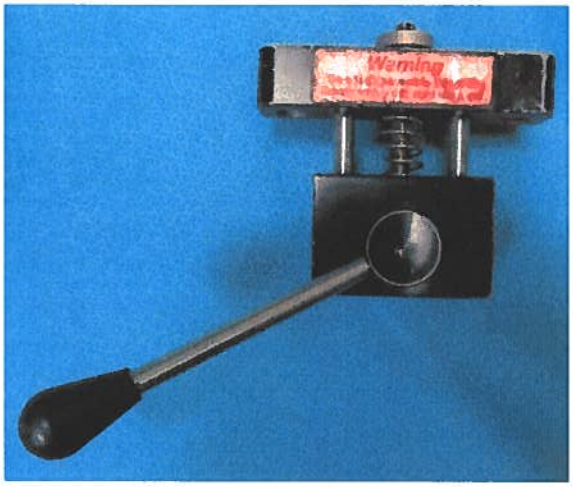

FIGURE 2

Using gloved hands soiled with artificial test soil, the surface of the device was handled, ensuring contact with difficult to clean areas. The device was actuated when distributing soil to simulate actual use. The total volume of soil used for inoculation was recorded. The underside of the base plate was not soiled as this surface did not see clinical soiling.

PROTEIN CLEANING RESULTS (µg/cm²)

Sample ID	Test Sample	Efficacy Cycle 1	Efficacy Cycle 2	Efficacy Cycle 3
DeMayo Knee Positioner Base w/ 903 Single Lever Clamp	1	<0.135	<0.135	<0.135
	2	<0.135	<0.135	<0.135
	3	<0.135	<0.135	<0.135
	Positive Control	249.473		
	Negative Control	<0.135		

TABLE 4