# PASSIVATION VALIDATION REPORT

(FM/VRP-102)

SURGICON (Pvt) Ltd

Khadim Ali Road Sialkot, Pakistan

**Approval**

| | NAME | DATE | SIGNATURE |
|---|---|---|---|
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**INTRODUCTION:**

Passivation is a non-electrolytic finishing process that makes stainless steel more rust-resistant. The passivation process typically uses nitric or citric acid to remove free iron from the surface. This results an inert, protective oxide layer that is less likely to chemically react with air and cause corrosion. By chemically removing free irons from the surface of stainless steel, the passivation process adds a thin oxide "film" layer. Less iron at the surface means more chromium. More chromium means a thicker chromium oxide surface when the stainless steel is exposed to air (oxygen). And that thicker, chemically non-reactive surface means more protection against rust.

**OBJECTIVES:**

It is required to passivate our Instruments within the quality range of ISO standards using calculated volume of chemicals, time & temperature.

**PRODUCTS TO BE COVERED:**

Stainless Steel forceps, Needle holders, Allis forceps, Tissue forceps, BP handle, Cusco Speculum, Elevators, Nail Cutters, Pliers, dental extracting forceps, Elevators Probes all kinds of scissors, single Items, General Items and other single use &re usable instruments etc.

**EQUIPMET/PROCESS TO BE VALIDATED:**

Passivation Process

CHEMICAL: Nitric acid (400 litters) +Sodium dichromate (2 gram)

WATER: 1000 Litters

NUMBER OF TANK USED: 01 tank (90x45x50 cm)

TANK CAPACITY: 1400 Litters

TEMPERATURE: 20-50 °C

TIME: 20-30 min

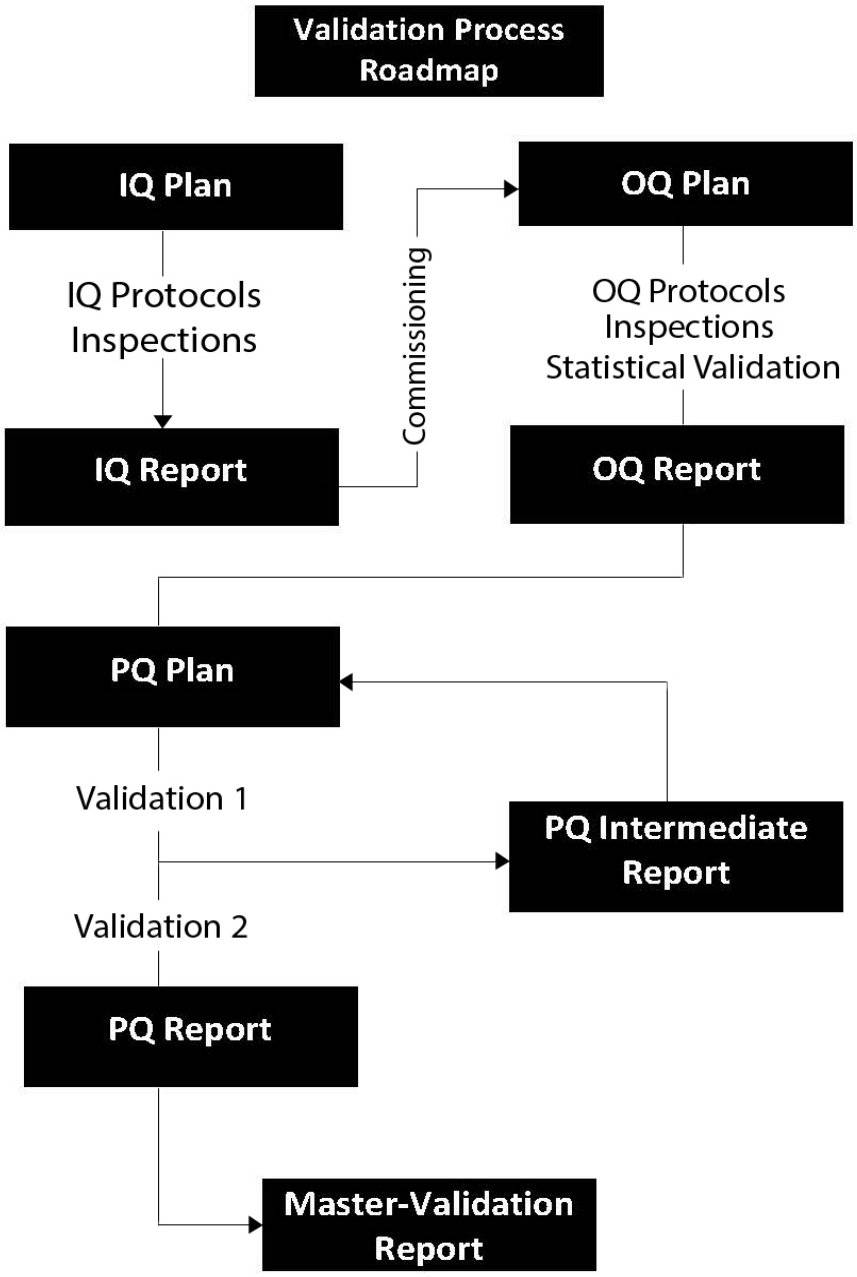
## VALIDATION TEAM PROTOCOAL

| | |
|---|---|
| _____ | _____ |
| Imtinan Jilani<br>(Director Marketing) | Abdul Wahid<br>(General Manager) |
| _____ | _____ |
| M. Arshad Malik<br>(QA & RA Manager) | Sohail Javed<br>(Machine Operator) |

## VALIDATION PLAN:

Passivation process will be subjected to installation qualification, operational qualification, and performance qualification.

The **Installation Qualification**: utilize the Machine operating manual used for Passivation process to define requirements for chemical parameters, time and temperatures.



The second phase of **Operational Qualification** will determine the sensitivity of the process to variation in time and temperature. The ideal production process will be used. Worst – case combination of time and temperature will be evaluated. Runs will be completed 1: with the optimal setting, 2: with a short time dwell, high temperature, 3: with a long time dwell and low temperature. Action level for the adjustment of Passivation process will be determined as a result of this phase.

**Performance Qualification:** will commence after satisfactory completion of operational qualification. Optimal setting for Passivation process will be used and samples will be subjected to Passivation and results will be determined. When process stability is demonstrated and process gives results in the required range the process will be validated and will be used to control the process.

## INSTALLATION QUALIFICATION:

**SELECTION OF DEVICES: Choice of Instruments.**

A number of instruments from the range sold by the company were assembled to represent the various groups and classes of instruments. Each selected instrument was intended to represent the most difficult aspects of the Passivation process for that group. For example, Sponge Holding Forceps 24 cm will cover the range of our all the small sizes items etc. However the features of some of the instruments can also be used to demonstrate compliance of the other instruments not categorised in their group. The instruments selected are listed in the Table 1.

## Risk Analysis:

A risk analysis was then done to identify the features considered to require validation of reprocessing capability. If these features pass validation then other instruments containing any of those features are considered to have been validated. **Table 1 - Selected Instruments.**

| Device Name | Description and characteristics. |
|---|---|
| Sponge Holding Forceps 24 cm | These are locking forceps adapted for a variety of purposes including holding and positioning of swab, grasping and manipulating cervical tissues. |
| Lister Bandage Scissors 14.5 cm | Specialized scissors adapted to cut heavy or thick bandaging, especially to remove them from patients. They are also widely used to remove orthopaedic casting. |
| Adson Toothed Forceps 12 cm( General Surgery instruments) | These forceps are adapted to grasping fascia, heavier tissues and handling larger needles. They are generally used for tasks such as perinea surgery and the removal of stones from gall bladder |

| | |
|---|---|
| Apical Elevator<br>( Dental Instruments) | Used to loosen the tooth from the periodontal Socket |

## Measurement/Testing Equipment/Calibration:

1) **Temperature:**
   There is only one tank used for Passivation process and the temperature of the tank lies in the range between 20 °C to 50 °C. Above these temperatures, causes defects on the surface of the instruments.

2) **Volume of Container:**
   There is only one tank containing water (1000 litters), Nitric acid (400 litters) and sodium dichromate (2 gram). So total capacity or working volume of tank is 1400 Litters.

3) **Time**:
   Time for Passivation process lies in the range between 20 min to 30 min depend upon the size of the instruments. So we consider the above timing is ideal for the Passivation process.

## REVALIDATION:

Upon completion of validation, the process validation plan will be updated to include the validation of Passivation process in the master validation schedule.

## OPERATIONAL QUALIFICATION RESULTS:

**Phase 1.**

| Sr# | Product Code | Lot # | Qty | Time(min) | Temperature(°C ) | Result |
|---|---|---|---|---|---|---|
| 1 | j-17-044 (Forcep) | A24346 | 500 | 25 | 35 | Better |
| 2 | j-17-048(Forcep) | A24506 | 639 | 25 | 35 | Better |
| 3 | j-22-063(scissor) | A24263 | 593 | 25 | 35 | Better |
| 4 | j-22-001(scissor) | A24174 | 600 | 25 | 35 | Better |
| 5 | j-16-031(Tweezer) | A23968 | 491 | 15 | 25 | Better |
| 6 | j-16-014(Tweezer) | A23917 | 450 | 15 | 25 | Better |
| 7 | j-33-040(Roser koni) | A24309 | 100 | 25 | 40 | Better |
| 8 | J-19-315(Retractor) | A24353 | 57 | 25 | 40 | Better |

**Phase 2.**

| Sr# | Product Code | Lot # | Qty | Time(min) | Temperature(°C ) | Result |
|---|---|---|---|---|---|---|
| 1 | j-35-740 (Forcep) | A23911 | 247 | 30 | 40 | Excellent |
| 2 | j-24-001(Forcep) | A24497 | 654 | 30 | 40 | Excellent |
| 3 | j-22-212(scissor) | A24264 | 596 | 30 | 40 | Excellent |
| 4 | j-22-002(scissor) | A24176 | 700 | 30 | 40 | Excellent |
| 5 | j-16-002(Tweezer) | A23970 | 864 | 20 | 30 | Excellent |
| 6 | j-16-024(Tweezer) | A24093 | 542 | 20 | 30 | Excellent |
| 7 | Jo-21-2733(Bone holding) | A24055 | 51 | 30 | 50 | Excellent |
| 8 | SD-0409-18(Extraction forcep) | A24102 | 55 | 30 | 50 | Excellent |

**Phase 3.**

| Sr# | Product Code | Lot # | Qty | Time(min) | Temperature(°C ) | Result |
|---|---|---|---|---|---|---|
| 1 | j-18-0265(Forcep) | A24476 | 625 | 15 | 30 | Not Good |
| 2 | j-22-745095bs (scissor) | A23951 | 240 | 15 | 30 | Not Good |
| 3 | j-16-341212 (Tweezer) | A24082 | 1000 | 10 | 20 | Not Good |
| 4 | Sv-3052-03 (Distractor) | A24025 | 93 | 40 | 60 | Not Good |

## IDEAL CASE:

Passivate instruments in 1400 litters of tank between Temperature Range 20 degree to 50 degree centigrade and Time interval between 20 min to 30 min depend upon the size of the instruments.

## UPPER WORST CASE:

Passivate more instruments in 1400 litters of tank above Temperature Range 20 degree to 50 degree centigrade and above Time interval between 20 min to 30 min.

## Phase 2:

Ideal Case production process was used to passivate the products and passivation process setting was at.

i) Temperature Range between 20°C to 50°C.
ii) Time 20 min to 30 min depend upon the size of the instruments.
iii) Volume of chemical consists of Nitric acid (400 litters), Sodium dichromate (2 gram) & water (1000 litters)

## Results:

The run with optimal setting results in a good and desired passivation surface appearance.

Passivation process Operational Qualification was successful.

## Performance Qualification:

Normal production of Mentioned products was run at optimal ideal settings. Results obtained were control charted. Following are control tables shown below

| Sr# | Product Code | Time(min) | Temperature(°C ) | Result |
|---|---|---|---|---|
| 1 | Forcep | 30 | 40 | Excellent |
| 2 | scissor | 30 | 40 | Excellent |
| 3 | Tweezer | 20 | 30 | Excellent |
| 4 | Bone holding | 30 | 50 | Excellent |
| 5 | Extraction forcep | 30 | 50 | Excellent |

## Result:

The process has demonstrated stability. The process validation plan has been updated to include the validation of Passivation process.

# Inspection of the Passivated Lot:

We check the passivated lot by following method to verify the corrosion resistance.

As referred by the standard ASTM-F-1089-10 & ISO-13402 We use the boil test method for the checking the corrosion resistance.

### 1: Boil Test Procedure:

This process is usually done at the final stages of the production. (SOP-39)

i) Clean the instruments with warm & clean water.
ii) Immerse the instruments in clean water in the boiling tank and at least 1/2 hour keeping the water boiling and hold the instruments in this tank from 3-4 hours to cool down the instruments.
iii) Remove the instruments from the tank and keep these in open air on the table for at least 2 hour.
iv) After drying the instruments will examine it visually for any evidence of the corrosion.
v) Check any blemish on the surface which was left even after rubbing for evidence of corrosion.

**Results**: In boil test following parameters checked

i) Sign of rust.
ii) Sign of pitting.
iii) Discoloration.

## Conclusion:

All the lots have passed our inspection criteria, its mean that the passivation process is validated properly.

## Validation Results Approval:

We have reviewed the requirements of the protocol; the IQ, OQ and PQ reports and compared these to the requirements of the reference documents. All requirements have been met and the process is validated.

## VALIDATION TEAM PROTOCOAL

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**Date: 10/06/2024**