Robertsite®
Needlefree Valves

HALKEY | ROBERTS®
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Instructions for Use

Accessing the Swabable Valve

Single Use Only. Do not reprocess or reuse.
Not made with natural rubber latex.

Cautions:
- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
- Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
  A standard luer connection must conform to the harmonized standards, ISO 594-1 and/or ISO 594-2. Syringes and male luer connectors have a large variety of configurations and can vary significantly in design and dimensions.
- **DO NOT OVER-TIGHTEN** connections. **DO NOT USE** any instruments to tighten connections.

1. Using aseptic technique, remove the sterile device from the package. Discard if packaging is not intact.
2. Using a sterile alcohol wipe, swab the surface of the valve (*illustration 1*). Let it air dry.
3. Carefully connect the syringe or extension set to the valve by pushing the syringe or other Luer connection **straight** into the swabable valve using a clockwise, twisting motion. **DO NOT** try to insert at an angle or try to pry open the slit in the valve.
   - Note: When using rotating collar MLL connectors ensure that collar is rotated and connection is secure.
   - (*See illustrations 2 (a and b) and 3 (a and b) for proper accessing techniques.*)

4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.
5. Flush the swabable valve device after each use per facility protocol.
6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

All HR Medical Components are shipped bulk, non-sterile and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, appropriateness of the component in the final application, and pre/post shelf life.

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LT245-001, Rev. F
Cautions:
• To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
• Carefully follow the directions below to maintain the valve integrity.
• Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
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Cautions:

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LT245-007, Rev. E
Cautions:

- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
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<table>
<thead>
<tr>
<th>Male Slip Luer (MSL)</th>
<th>Male Luer Lock (MLL)</th>
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<tbody>
<tr>
<td><img src="#" alt="ill. 2a" /></td>
<td><img src="#" alt="ill. 2b" /></td>
</tr>
<tr>
<td><img src="#" alt="ill. 3a" /></td>
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5. Flush the swabable valve device after each use per facility protocol.
6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

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6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

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LT245-005, Rev. D
**Cautions:**

- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
- Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
  - A standard luer connection must conform to the harmonized standards, ISO 594-1 and/or ISO 594-2. Syringes and male luer connectors have a large variety of configurations and can vary significantly in design and dimensions.
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   ![Male Slip Luer (MSL)](image1) ![Male Luer Lock (MLL)](image2)

4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.
5. Flush the swabable valve device after each use per facility protocol.
6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

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LT245-010, Rev. D
Robertsite® Needlefree Injection Site Valves

Instructions for Use
Accessing the Swabable Valve

Single Use Only. Do not reprocess or reuse.
Not made with natural rubber latex.
The Robertsite® valve is used in several different medical devices.
The technique for accessing the valve is the same.

Cautions:
• To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
• Carefully follow the directions below to maintain the valve integrity.
• Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
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   Note: When using rotating collar MLL connectors ensure that collar is rotated and connection is secure.
   *(See illustrations 2 (a and b) and 3 (a and b) for proper accessing techniques.)*

4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.
5. Flush the swabable valve device after each use per facility protocol.
6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

All HR® Medical Components are shipped bulk, non-sterile and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, appropriateness of the component in the final application, and pre/post shelf life.

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Cat. No.: 245424024, 245425024, 245425024B, 245454024, 245464024, 245474024
Cautions:

- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
- Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
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   - Note: When using rotating collar MLL connectors ensure that collar is rotated and connection is secure.
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The Robertsite® valve is used in several different medical devices. The technique for accessing the valve is the same.

Single Use Only. Do not reprocess or reuse. Not made with natural rubber latex.

Instructions for Use

**Stopcock with Swabable Valve**

**Cautions:**
- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
- Only use standard Luer connection devices; non-standard syringes or connectors can damage the swabable valve.
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- **DO NOT OVER-TIGHTEN** connections. **DO NOT USE** any instruments to tighten connections.

**INSTRUCTIONS FOR USE:**

**Fluid Management in 4-Way Stopcock**

1. Prime the stopcock before use. Approximate priming volume is 0.25ml. Ensure that all air bubbles are removed.
2. The molded arrows on the stopcock handles indicate the open flow paths in relation to the 3 ports. Turning the stopcock handle to the intermediate position, as shown in Illustration 1, can close all fluid paths.
3. Attach IV fluid device(s). Follow the specific Robertsite® instructions below. Ensure that all connections are secure.

4. **ROTATE THE HANDLE TO THE SELECTED FLOW PATH SETTING.** See illustrations 2 through 5, for 4-way flow options.

**Accessing the Robertsite® Swabable Valve**

1. Using aseptic technique, remove the sterile device from the package. Discard if packaging is not intact.
2. Using a sterile alcohol wipe, swab the surface of the valve (*illustration 6*). Let it air dry.
3. Carefully connect the syringe or extension set to the valve by pushing the syringe or other Luer connection **straight** into the swabable valve using a clockwise, twisting motion. **DO NOT** try to insert at an angle or try to pry open the slit in the valve.
   (See *illustrations 7 (a and b)* and *8 (a and b)* for proper accessing techniques.)

   **Male Slip Luer (MSL)**

   **Male Luer Lock (MLL)**

4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.
5. Flush the swabable valve device after each use per facility protocol.
6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

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  A standard luer connection must conform to the harmonized standards, ISO 594-1 and/or ISO 594-2. Syringes and male luer connectors have a large variety of configurations and can vary significantly in design and dimensions.
• **DO NOT OVER-TIGHTEN** connections. **DO NOT USE** any instruments to tighten connections.

INSTRUCTIONS FOR USE:

**Fluid Management in 4-Way Stopcock**
1. Prime the stopcock before use. Approximate priming volume is 0.25ml. Ensure that all air bubbles are removed.
2. The molded arrows on the stopcock handles indicate the open flow paths in relation to the 3 ports. Turning the stopcock handle to the intermediate position, as shown in Illustration 1, can close all fluid paths.
3. Attach IV fluid device(s). Follow the specific Robertsite® instructions below. Ensure that all connections are secure.
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**Accessing the Robertsite® Swabable Valve**
1. Using aseptic technique, remove the sterile device from the package. Discard if packaging is not intact.
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   (See illustrations 7 (a and b) and 8 (a and b) for proper accessing techniques.)
4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.
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6. Change swabable device per facility protocol.
7. Dispose of used device per facility protocol for biocontaminated materials.

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5. Flush the swabable valve device after each use per facility protocol.
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   Note: When using rotating collar MLL connectors ensure that collar is rotated and connection is secure.

   (See illustrations 2 (a and b) for proper accessing techniques.)

4. Twist counterclockwise to disconnect. The swabable valve completely closes after each use and therefore does not require a separate injection site cap.

5. Flush the swabable valve device after each use per facility protocol.

6. Change swabable device per facility protocol.

7. Dispose of used device per facility protocol for biocontaminated materials.

---

**Cautions:**

- To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swabable valve.
- Carefully follow the directions below to maintain the valve integrity.
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- **DO NOT OVER-TIGHTEN** connections. **DO NOT USE** any instruments to tighten connections.

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**Primbing Procedure - Use Aseptic Technique:**

Prime set by attaching to top most port (illustration 3) and allowing fluid to fill entire set.

Note: Entrained air may be removed by inverting and tapping. Needlefree injection sites may be primed using a flush syringe.

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**Secondary Infusions and Preparation of Needlefree Injection Sites:**

Manifolds have in-line gravity check valves on top most port and one-way injection side ports (infusion via gravity, syringe, or pump)

1. Prime a secondary set or syringe in the usual manner.

2. Swab septum with preferred antiseptic and allow to dry, or remove injection site cap.

3. Expel air as needed.

4. Attach secondary set and infuse desired amount of fluid.

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5. Twist to disconnect. The swappable valve completely closes after each use and therefore does not require a separate injection site cap. 
6. Flush the swappable valve after each use per facility protocol. 
7. Change swappable valve per facility protocol. 
8. Dispose of used valve per facility protocol for bioccontaminated materials.

Cautions:
• To prevent valve damage, **DO NOT USE** needles or blunt cannula to access the swappable valve.
• Carefully follow the directions below to maintain the valve integrity.
• Only use catheter or Toomey connection devices; non-standard syringes or connectors can damage the swappable valve. Syringes and male luer connectors have a large variety of configurations and can vary significantly in design and dimensions.
• **DO NOT OVER-TIGHTEN** connections. **DO NOT USE** any instruments to tighten connections.

All HR® Medical Components are shipped bulk, non-sterile and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, appropriateness of the component in the final application, and pre/post shelf life.
SWABABLE STRAIGHT VALVE

GENERAL CHARACTERISTICS
- Halkey-Roberts new swabable luer valves were developed as needle-free injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Straight valves are available in polycarbonate or BPA-free copolyester for easy bonding.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

MATERIALS
- Swabable Stem: Blue Silicone
- Swabable Body:
  - Suffix 24: Clear Polycarbonate
  - Suffix 50: Clear Copolyester
- Red Body: Clear Polycarbonate, red tint

PACKAGING AND SHIPPING
- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

POTENTIAL STERILIZATION METHOD
- ETO and Gamma, based on raw material manufacturer’s data

STRAIGHT SWABABLE VALVE
PART NUMBERS:
- 245204024  Polycarbonate
- 245204050  Copolyester
- 245204124  Polycarbonate (red body)

PERFORMANCE CHARACTERISTICS
- Priming volume: 0.09 ml

Flow Rate Averages
- Flow Rate @ 1 psi: 550 ml/minute (30,000/hr @ 30 inch height)
- Flow Rate @ 3 psi: 1000 ml/minute
- Flow Rate @ 5 psi: 1300 ml/minute

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**GENERAL CHARACTERISTICS**

- Halkey-Roberts new swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The ‘Y’ port valves are available in polycarbonate or in BPA-free copolyester for easy bonding.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible International Standard ISO 594.

**‘Y’ PORT SWABABLE VALVE**

**PART NUMBER:**
- 245624024  Polycarbonate (0.160 inch ID [4.01mm])
- 245624050  Copolyester (0.160 inch ID [4.01mm])
- 245634024  Polycarbonate (0.142 inch ID [3.6mm])

**PERFORMANCE CHARACTERISTICS**

- Priming volume (without tubing): 0.19 ml

**Flow Rate Averages**

- Flow Rate @ 1 psi: 410 ml/minute (24,600 ml/hr @ 30 inch height)
- Flow Rate @ 3 psi: 710 ml/minute
- Flow Rate @ 5 psi: 930 ml/minute

**MATERIALS**

- Swabable Stem: Blue silicone
- Swabable Body:
  - Suffix 24: Clear polycarbonate
  - Suffix 50: Copolyester

**PACKAGING AND SHIPPING**

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**

- ETO and Gamma, based on raw material manufacturer’s data

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**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**245 SERIES SWABABLE VALVES**

**TUBE END VALVE**

**GENERAL CHARACTERISTICS**
- Halkey-Roberts new swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Tube end valves are available in polycarbonate.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

**TUBE END SWABABLE VALVE**

**PART NUMBER:**
- 245520024 2.0 mm (0.079 inch)
- 245525024 2.5 mm (0.098 inch)
- 245528024 2.8 mm (0.110 inch)
- 245537024 3.7 mm (0.145 inch)
- 245540024 4.1 mm (0.160 inch)
* all sizes also available with red cap

**PERFORMANCE CHARACTERISTICS**
- Priming volumes (without tubing):
  - 2.0, 2.5, 2.8 mm = 0.12 ml
  - 3.7 mm = 0.22 ml
  - 4.0 mm = 0.24 ml

<table>
<thead>
<tr>
<th>Flow Rate Averages</th>
<th>1 psi</th>
<th>3 psi</th>
<th>5 psi</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.0 mm (ml/min)</td>
<td>270</td>
<td>480</td>
<td>630</td>
</tr>
<tr>
<td>2.5 mm (ml/min)</td>
<td>380</td>
<td>700</td>
<td>900</td>
</tr>
<tr>
<td>2.8 mm (ml/min)</td>
<td>470</td>
<td>830</td>
<td>1070</td>
</tr>
<tr>
<td>3.7 mm (ml/min)</td>
<td>480</td>
<td>840</td>
<td>1110</td>
</tr>
<tr>
<td>4.1 mm (ml/min)</td>
<td>510</td>
<td>890</td>
<td>1190</td>
</tr>
</tbody>
</table>

**PACKAGING AND SHIPPING**
- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**MATERIALS**
- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate

**POTENTIAL STERILIZATION METHOD**
- ETO and Gamma, based on raw material manufacturer’s data

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**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
GENERAL CHARACTERISTICS
- Halkey-Roberts swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap.
- The Bondable valve is designed to be bonded to ANSI/ISO or compatible standard female luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Bondable valve is available in polycarbonate with a red, blue or clear cap.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

BONDABLE VALVE

PART NUMBER:
- 245501024 – clear cap
- 245501024R – red cap
- 245501024B – blue cap

PERFORMANCE CHARACTERISTICS
- Priming volume (without tubing): < 0.13 ml

Flow Rate Averages
- Flow Rate @ 1 psi: 440 ml/minute (26,400 ml/hr @ 30 inch height)
- Flow Rate @ 3 psi: 810 ml/minute
- Flow Rate @ 5 psi: 1010 ml/minute

MATERIALS
- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate
- Swabable Luer:
  - Clear Polycarbonate
  - Clear Polycarbonate with Red Tint
  - Clear Polycarbonate with Blue Tint

PACKAGING AND SHIPPING
- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

POTENTIAL STERILIZATION METHOD
- ETO and Gamma, based on raw material manufacturer’s data

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**GENERAL CHARACTERISTICS**

- Halkey-Roberts needlefree bag access valves are designed to attach directly to the solution bag during their production. These swabable valves can be used as needlefree injection sites or to access the bag with a mating luer connector, eliminating the need for spike ports and needles.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Bag valve is available in polycarbonate for easy bonding.
- Tubing port is designed for 6.8mm (.268 inch) I.D. tube ports.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible International Standard ISO 594.

**SWABABLE BAG VALVE**

**PART NUMBER:**
- 245110024

**PERFORMANCE CHARACTERISTICS**

- Priming volume (without tubing): 0.25 ml

**Flow Rate Averages**
- Flow Rate @ 1 psi: 520 ml/minute (31,200 ml/hr @ 30 inch height)
- Flow Rate @ 3 psi: 920 ml/minute
- Flow Rate @ 5 psi: 1220 ml/minute

**MATERIALS**

- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate

**PACKAGING AND SHIPPING**

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**

- ETO and Gamma, based on raw material manufacturer’s data

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Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

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January 2015
SWABABLE BREAK-OFF VALVE

General Characteristics

- Halkey-Roberts needlefree break-off valves are designed to attach directly to the solution bag during their production. These swabable valves can be used as needlefree injection sites or to access the bag with a mating luer connector, eliminating the need for spike ports and needles.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Break-off valve is available in polycarbonate for easy bonding.
- The break-off valves are designed to fit two tubing sizes: 6.0 mm and 6.6 mm I.D.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

SWABABLE BREAK-OFF VALVE

BREAK-OFF VALVE  
PART NUMBER:

- 245112024  6.0 mm
- 245113024  6.6 mm

PERFORMANCE CHARACTERISTICS

- Priming volume: 0.30 ml

Flow Rate Averages

- Flow Rate @ 1 psi: 240 ml/minute (14,400 ml/hr @ 30 inch height)
- Flow Rate @ 3 psi: 430 ml/minute
- Flow Rate @ 5 psi: 550 ml/minute

MATERIALS

- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate

PACKAGING AND SHIPPING

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

POTENTIAL STERILIZATION METHOD

- ETO and Gamma, based on raw material manufacturer’s data

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
20MM SWABABLE VIAL CAP

GENERAL CHARACTERISTICS

- Halkey-Roberts new swappable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Vial caps are available in polycarbonate.
- The Swabbable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

20MM SWABABLE VIAL CAP

PART NUMBER:
- 245700021

PERFORMANCE CHARACTERISTICS

- Priming volume: 0.06 mL
- Flow Rate Averages
  - Flow Rate @ 1 psi 200 mL/minute
  - Flow Rate @ 3 psi 340 mL/minute
  - Flow Rate @ 5 psi 420 mL/minute

MATERIALS

- Swappable Stem: Blue Silicone
- Swappable Body: Clear Polycarbonate

PACKAGING AND SHIPPING

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

POTENTIAL STERILIZATION METHOD

- ETO and Gamma, based on raw material manufacturer’s data

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
13MM SWABABLE VIAL CAP

**GENERAL CHARACTERISTICS**
- Halkey-Roberts new swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Vial caps are available in polycarbonate.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

**PERFORMANCE CHARACTERISTICS**
- Priming volume: 0.06 mL
- Flow Rate averages:
  - Flow Rate @ 1 psi: 200 ml/minute
  - Flow Rate @ 3 psi: 400 ml/minute
  - Flow Rate @ 5 psi: 500 ml/minute

**MATERIALS**
- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate

**PACKAGING AND SHIPPING**
- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**
- ETO and Gamma, based on raw material manufacturer’s data

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**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

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January 2015
## General Characteristics
- Halkey-Roberts new swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The T-Port valve is available in polycarbonate for easy bonding.
- Tubing port is designed for 6.8mm (.268 inch) O.D. tubing.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

### Performance Characteristics
- Priming volume: < 0.15 ml

### Flow Rate Averages
- Flow Rate @ 1 psi: 540 ml/minute (32,400 ml/hr @ 30 inch height)
- Flow Rate @ 3 psi: 950 ml/minute
- Flow Rate @ 5 psi: 1200 ml/minute

### Materials
- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate
- Swabable Luer Body:
  - Clear Polycarbonate
  - Clear Polycarbonate with red tint
  - Clear Polycarbonate with blue tint

### Packaging and Shipping
- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

### Potential Sterilization Method
- ETO and Gamma, based on raw material manufacturer’s data

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**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
SWABABLE T-PORT – SMALL-BORE TUBING

GENERAL CHARACTERISTICS

- Halkey-Roberts new swabable luer valves were developed as needlefree injection ports in IV applications. They are designed to aspirate or inject fluids on demand. The valves allow multiple usage and require no cap. Valve stems and bodies will mate securely with all standard luer syringes and luer connectors.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Small Bore T-Port valve is available in polycarbonate for easy bonding.
- The Small Bore T-Ports are designed for 4.0/4.1 mm (0.157/0.161 inch) O.D. tubing, 3.2 mm (0.126 inch) O.D. tubing and 2.1 mm (0.082 inch) O.D. tubing.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

P/N 245454024     4.0/4.1 mm
P/N 245474024     3.2 mm
P/N 245464024     2.0 mm

SMALL BORE T-PORT VALVES

PERFORMANCE CHARACTERISTICS

- Priming volume: < 0.15 ml

FLOW RATE AVERAGES

<table>
<thead>
<tr>
<th>PSI [BAR]</th>
<th>1 psi</th>
<th>3 psi</th>
<th>5 psi</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.0/4.1mm (mL/min) and 3.2mm (mL/min)</td>
<td>540</td>
<td>950</td>
<td>1200</td>
</tr>
<tr>
<td>2.1mm (mL/min) **</td>
<td>104</td>
<td>187</td>
<td>239</td>
</tr>
</tbody>
</table>

** Flow is with 1mm ID tubing

MATERIALS

- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate
- Swabable Luer Body: Clear Polycarbonate

PACKAGING AND SHIPPING

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

POTENTIAL STERILIZATION METHOD

- ETO and Gamma, based on raw material manufacturer’s data

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**GENERAL CHARACTERISTICS**

- Halkey-Roberts new needlefree swabable Barbs are ideal for use as sampling ports in biopharmaceutical applications and are designed for easy assembly directly to tubing without the use of a luer connector or solvents and adhesives.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- The Barb valves are available in polycarbonate for easy bonding.
- The Barbs are available in a 1/4 inch, 3/16 inch and a 1/8 inch version.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

**PERFORMANCE CHARACTERISTICS**

**Priming Volume**
- Priming volume: 0.30 mL

**FLOW RATE AVERAGES**

<table>
<thead>
<tr>
<th>PSI [BAR]</th>
<th>1/4 inch (ml/min)</th>
<th>3 [0.20]</th>
<th>5 [0.34]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 psi</td>
<td>559</td>
<td>1012</td>
<td>1334</td>
</tr>
<tr>
<td>1/4 inch</td>
<td>658</td>
<td>1038</td>
<td>1108</td>
</tr>
<tr>
<td>3 psi</td>
<td>3/16 inch (ml/min)654</td>
<td>1038</td>
<td>1108</td>
</tr>
<tr>
<td>3/16 inch</td>
<td>367</td>
<td>654</td>
<td>857</td>
</tr>
<tr>
<td>5 psi</td>
<td>1/8 inch (ml/min) 367</td>
<td>654</td>
<td>857</td>
</tr>
<tr>
<td>1/8 inch</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**MATERIALS**

- Swabable Stem: Blue Silicone
- Swabable Body: Clear Polycarbonate
- Swabable Luer Body: Clear Polycarbonate

**PACKAGING AND SHIPPING**

- Valves are bulk packaged, double bagged in clean, closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**

- ETO and Gamma, based on raw material manufacturer’s data

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**GENERAL CHARACTERISTICS**

- Halkey-Roberts 4-Way Lever Swabable Luer Activated Stopcock provides the safety of a closed system with a leak-free aseptic swabable port. The needlefree access port can be swabbed in order to maintain a sterile barrier. We have incorporated our swabable technology into the stopcock to provide our customers with another easy to use needlefree access product.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

**SWABABLE LEVER STOPCOCK**

**PART NUMBERS & DESCRIPTION**

- 245814024W (white)
- 245814024R (red)
- 245814024B (blue)
- 245814024Y (yellow)

**PERFORMANCE CHARACTERISTICS**

- Priming volume: 0.3 ml

**Flow Rate Averages**

- Flow Rate: @ 1 psi: 255 ml/minute
- Flow Rate: @ 3 psi: 450 ml/minute
- Flow Rate: @ 5 psi: 650 ml/minute

**MATERIALS**

- Swabable Stem: Blue Silicone
- Stopcock Body and Cap: Clear polycarbonate
- Handle: HDPE

**PACKAGING AND SHIPPING**

- Valves are bulk packaged, double bagged in clean closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**

- ETO and Gamma, based on raw material manufacturer’s data

---

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

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January 2015
# 4-WAY ‘T’ SWABABLE STOPCOCK

## General Characteristics
- Halkey-Roberts 4-Way ‘T’ Swabable Luer Activated Stopcock provides the safety of a closed system with a leak-free aseptic swabable port. The needlefree access port can be swabbed in order to maintain a sterile barrier. We have incorporated our swabable technology into the stopcock to provide our customers with another easy to use needlefree access product.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

## Swabable ‘T’ Stopcock

### Part Numbers & Description
- 245824024W (white)
- 245824024R (red)
- 245824024B (blue)
- 245824024Y (yellow)

## Performance Characteristics
- Priming Volume: 0.3 ml
- **Flow Rate Averages**
  - Flow Rate: @ 1 psi: 255 ml/minute
  - Flow Rate: @ 3 psi: 450 ml/minute
  - Flow Rate: @ 5 psi: 650 ml/minute

## Materials
- Swabable Stem: Blue Silicone
- Stopcock Body and Cap: Clear polycarbonate
- Handle: HDPE

## Packaging and Shipping
- Valves are bulk packaged, double bagged in clean closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

## Potential Sterilization Method
- ETO and Gamma, based on raw material manufacturer’s data

---

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**ROBERTSITE® SWABABLE BUILD-IN ASSEMBLY**

**GENERAL CHARACTERISTICS**
- Halkey-Roberts needlefree Build-In Assembly valves are designed to be ultrasonically welded to a modified mating component to create a low profile swabable access site.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and are not made with natural rubber latex.
- The valve is available in polycarbonate for easy ultrasonic welding.
- The Swabable Valve series is a medical component: bulk, non-sterile, for manufacturing processing or repacking only.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible with International Standard ISO 594.

**BUILD-IN ASSEMBLY**
PART NUMBER & DESCRIPTION
- 245680024 ROBERTSITE® BUILD-IN ASSEMBLY

**PERFORMANCE CHARACTERISTICS**
- **Priming Volume**
  - Priming volume (Valve only): < 0.2 mL
- **Flow Rate Average**
  - Flow Rate @ 1 psi: 656 mL/min
  - Flow Rate @ 3 psi: 1041 mL/min
  - Flow Rate @ 5 psi: 1319 mL/min

**MATERIALS**
- Swabable Stem: Blue Silicone
- Manifold Body and Cap: Clear Polycarbonate

**PACKAGING AND SHIPPING**
- Valves are bulk packaged, double bagged in clean closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**
- ETO and Gamma, based on raw material manufacturer’s data

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
**GENERAL CHARACTERISTICS**

- Halkey-Roberts MultiPort Manifold contains a total of 6 needlefree injection sites, along with a flow controlled inlet port. Each of the 6 needlefree injection sites has a back check valve integrated below the injection site. The inlet port also has a back check valve integrated as part of the inlet port.
- All materials are Gamma resistant, ISO 10993 compliant, DEHP-free and not made with natural rubber latex.
- Customer is responsible for the Qualification/Verification of the HR® medical component in their final device application.
- Luer fittings are compatible International Standard ISO 594.

**MULTI_PORT MANIFOLD**

**PART NUMBER & DESCRIPTION**

- 245800912 ROBERTSITE® MULTI_PORT MANIFOLD

**PERFORMANCE CHARACTERISTICS**

**Flow Rate Average**

- Flow Rate (1 injection port) @ 1 psi: 229 ml/min
- Flow Rate (1 injection port) @ 3 psi: 407 ml/min
- Flow Rate (1 injection port) @ 5 psi: 525 ml/min

**Priming Volume (without tubing)**

- Manifold Only = 1.4 mL

**Check Valve Crack Pressures**

- Forward flow at 12 in H2O or greater
- No retrograde flow at 12 in H2O or greater

**MATERIALS**

- Swabable Stem: Blue Silicone
- Manifold Body and Cap: Clear Polycarbonate
- Check valve: Polyisoprene

**PACKAGING AND SHIPPING**

- Manifolds are bulk packaged, double bagged in clean closed polybags
- Shipping container is clearly labeled with HR® part number, lot number and quantity

**POTENTIAL STERILIZATION METHOD**

- ETO and Gamma, based on raw material manufacturer’s data

---

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
Robertsite® Needlefree Swabable Valve

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

Issued: 1/1/2012
Halkey-Roberts Swabable Valve

The Halkey-Roberts Swabable Valve features a very simple and unique design. Only three components allow for economical assembly and the unique design provides for the highest flow rates.

- Female body is molded of lipid resistant polycarbonate or BPA-free copolyester
- Sealing stem is molded from silicone
- Male body is molded of lipid resistant polycarbonate or BPA-free copolyester
- Components are sonic welded together for high reliability and safety

The valve is constructed of materials that are USP class VI, do not contain natural rubber latex, are DEHP free and will mate securely with all standard luer syringes and luer connectors providing a hermetic seal between the luer tip and valve.

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
Swabable Valve Operation

Features:
- High flow
- Easy access with either slip luer or luer lock syringes
- Low priming volume
- Straight through design for unimpeded flow

Important: All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.
### SWABABLE PRODUCT LINE

<table>
<thead>
<tr>
<th>Straight Valves</th>
<th>Y-Port Valves</th>
<th>Tube End Valves</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Straight Valves" /></td>
<td><img src="image2" alt="Y-Port Valves" /></td>
<td><img src="image3" alt="Tube End Valves" /></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Vial Cap Valves</th>
<th>T-Port Valves</th>
<th>Small-Bore T-Ports</th>
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</thead>
<tbody>
<tr>
<td><img src="image4" alt="Vial Cap Valves" /></td>
<td><img src="image5" alt="T-Port Valves" /></td>
<td><img src="image6" alt="Small-Bore T-Ports" /></td>
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</tbody>
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<table>
<thead>
<tr>
<th>Break-Off Valves</th>
<th>Bag Valve</th>
<th>Bondable Valve</th>
</tr>
</thead>
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<tr>
<td><img src="image7" alt="Break-Off Valves" /></td>
<td><img src="image8" alt="Bag Valve" /></td>
<td><img src="image9" alt="Bondable Valve" /></td>
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<table>
<thead>
<tr>
<th>Barb Valves</th>
<th>Lever Handle Stopcock</th>
<th>‘T’ Handle Stopcock</th>
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<td><img src="image10" alt="Barb Valves" /></td>
<td><img src="image11" alt="Lever Handle Stopcock" /></td>
<td><img src="image12" alt="‘T’ Handle Stopcock" /></td>
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<thead>
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<th>Multiport Manifold</th>
<th>Transfer Valve</th>
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<tr>
<td><img src="image13" alt="Multiport Manifold" /></td>
<td><img src="image14" alt="Transfer Valve" /></td>
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</tbody>
</table>

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

Issued: 3/2015
### Summary of Biocompatibility Test Results
ISO 10993-1 Standard Testing Procedures

<table>
<thead>
<tr>
<th>Test performed</th>
<th>Interpretation</th>
<th>510(k)</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytotoxicity</td>
<td>The test article is considered non-cytotoxic</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td>Acute Systemic Toxicity</td>
<td>The test article extracts would not be considered systemically toxic</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td>Acute Intracutaneous Reactivity</td>
<td>No evidence of significant irritation or toxicity from the extracts injected</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>intracutaneously into rabbits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemolysis (direct contact and chemical)</td>
<td>The test article was determined to be non-hemolytic (less than 5%)</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td>Pyrogen Study – Material Mediated</td>
<td>The test article extract was judged as non-pyrogenic</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td>Guinea Pig Maximization</td>
<td>The test article showed no evidence of causing delayed dermal contact</td>
<td>K002689</td>
<td>Pass</td>
</tr>
<tr>
<td></td>
<td>sensitization in the guinea pig</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Robertsite® is a trademark of Halkey-Roberts Corporation

**Important:** All HR® Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

**Issued:** 5/11/11
ROBERTSITE® 7 DAY MICROBIAL CHALLENGE EVALUATION

Purpose:
To demonstrate the integrity of the Robertsite Luer Activated Injection Site (valve) microbial barrier properties after seven days (168 hours) of simulated worst case clinical use (140 activations) using a common nosocomial infection organism, Staphylococcus aureus.

Protocol Summary:
AppTec Laboratory Services, Marietta, GA, performed all laboratory testing.
Each of 20 devices was accessed 20 times per day for seven days (140 total activations) Each sample was challenged daily after repeated activations using approximately 1.0 x 10^3 colony forming units (CFU)/ 0.01 ml of the challenge organism (Staphylococcus aureus). After routine disinfection of the device, 10 ml of sterile saline was injected through it and passed through a .45µ membrane filter. The filters were incubated on Tryptic Soy Agar (TSA) at 30 - 35°C for 48 ± 4 hours and the colony forming units (CFUs) enumerated.

Method:
The study included two positive, two negative and three sterility control samples. Each of the test samples and positive controls were challenged using the simulated clinical use model. They were swabbed and accessed 20 times each day. Inoculation and CFU determinations were done after the last activation for the day, as well as the first activation on Day 1. Prior to each access the injection site of each valve was swabbed with a fresh sterile 70% isopropyl alcohol (IPA) pad folded once for 25 – 30 seconds followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline.

Inoculum: A fresh culture of Staphylococcus aureus was used each day. A suspension was prepared and diluted to approximately 1.0 x 10^3 Colony Forming Units (CFU)/ 0.01 ml for use as an inoculant and stored at 2-8°C. The inoculum population during the seven day test period ranged from 9.3 x 10^2 to 5.4 x 10^3 CFU / 0.01 ml.

Prior to inoculation of test samples and positive controls, each seal was swabbed as described above and was allowed to dry for a minimum of one (1) minute. 0.01 ml of inoculum was placed directly on the top of each valve. The inoculated sites were allowed to sit undisturbed for thirty minutes. Valves were then swabbed as described above with 70% IPA followed by drying for a minimum of one (1) minute. After drying, each valve was accessed using a new, sterile syringe and flushed with 10 ml of sterile saline. The saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 °C for 48 hours. Following the incubation period, the CFU’s for each valve filtrate were enumerated.
The negative controls were swabbed and accessed twenty times each day as described above. After the last access of the day, the saline was collected and filtered through a 0.45-micron membrane filter. The filter was placed on TSA and incubated at 30 – 35 °C for 48 hours. Following the incubation period, the CFU’s for each valve were counted.

The sterility controls (sterilized devices) were placed in 30 ml tubes of tryptic soy broth and incubated at 30 – 35 °C for seven days.

Results:
During the seven days and 140 accesses of the test study using the method described above, the Robertsite valve test samples and negative controls demonstrated no growth of the challenge organism. Positive controls exhibited growth typical of the challenge organism. The recovery ranged from 5 x 10^0 to 9.4 x 10^2 CFU with a mean count of 1.86 x 10^2 CFU. Sterility controls demonstrated absence of growth after seven days of incubation.

Conclusion:
The Robertsite Luer Activated Valve, when used with an adequate disinfection procedure, maintains its microbial barrier properties after 140 activations over a 7-day period. The study was conducted using a higher concentration of challenge organism than typically found in a hospital environment and a non-typical extended time period.

Clinical Use Recommendations: Follow the manufacturer’s recommendations in the Instructions For Use: For IV administration use, replace the injection site per CDC (FDA Center for Disease Control) guidelines or facility protocol.

Robertsite is a trademark of Halkey-Roberts Corporation

Important: All HRC Medical Components are shipped bulk, non-sterile, and are single patient use medical device components intended for further processing (e.g. further assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/reprocessing/multiple usage on these components and the appropriateness of the component in the final application.
FLUSHING STUDY FOR ROBERTSITE® SWABABLE VALVES

Purpose:
To demonstrate the flushing efficiency of Robertsite Swabable valves.

Tested samples were:
  o Halkey-Roberts Robertsite® “Swabable Straight Valve”

Protocol Summary:
AppTec Laboratory Services, St. Paul, MN, performed all laboratory testing.

Three (3) Halkey-Roberts Robertsite® “Swabable Straight Valves” were tested.

5 mL of human blood was aspirated through each valve. The valves were exposed to the blood for 10 minutes at room temperature. The blood was removed by the attached syringe immediately prior to initiation of flushing. Each valve was flushed with 1mL deionized water. The flushing was repeated five times. The eluates were collected into sample tubes and analyzed for total hemoglobin concentration and flushing efficiency (% clearance).

Method:
The study included positive and negative controls. The positive controls were filled with a solution of 5.0 mL of sterile water mixed with 0.35 mL of whole blood. The negative controls were filled with water only.

Test samples: 5 mL of blood was aspirated through each sample valve and left for 10 minutes at room temperature. The syringe was then removed immediately prior to flushing. The valve tip was blotted, and a new syringe with flushing fluid was attached. Each valve was flushed with 1 mL of deionized water and the flush was collected into labeled tubes. The flush was repeated five times. The hemoglobin concentration in the samples was determined using Drabkin’s reagent at 1:1 ratio. After a 15 minute incubation at room temperature, the absorbance of each sample was read using a spectrophotometer at a wavelength of 545 nm. Controls were tested concurrently.

The total hemoglobin concentration and % clearance were determined for each flush separately.

Results:
100 % clearance was achieved by the 3rd flush for the Halkey-Roberts Robertsite® “Swabable Straight Valve”

Conclusion:
The Robertsite valve has demonstrated that it can be effectively flushed using the methods performed in this study.

Robertsite® is a trademark of Halkey-Roberts Corp.

Robertsite U.S. patent nos. US 6,651,956 and 6,089,541.

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ROBERTSITE® MULTIPLE ACTIVATIONS EVALUATION

Purpose:
To demonstrate Robertsite Luer Activated Injection Site integrity after up to 300 activations.

Background:
Robertsite valves were accelerated heat aged for two years and tested for sealing performance after 300 activations.

Results:
Assembled Robertsite valves passed back pressure sealing performance testing after 2 years of accelerated heat aging followed with 100, 200 and 300 activations. The mean back pressure value was 48 psig. The -3σ values ranged from 44 to 46 psig. All samples fell within a +/-3σ distribution.

Conclusion:
The Robertsite valves were assembled per HRC production procedures and accessed by a standard luer (ISO594-1/-2) connectors. After 300 activations, all Robertsite devices passed the HRC specification for back pressure seal performance (30 psig minimum).

Clinical Use Recommendations:
Follow Halkey-Roberts’ recommendations in the Instructions for Use.

Robertsite® is a trademark of Halkey-Roberts Corporation
U.S. patent nos. US 6,651,956 and 6,089,541.

Important: All HRC Medical Components are shipped bulk, non-sterile, and are single patient use medical device components intended for further processing (e.g. further assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/reprocessing/multiple usage on these components and the appropriateness of the component in the final application.
**ROBERTSITE® STEM SHELF LIFE EVALUATION**

**Purpose:**
To demonstrate Robertsite Luer Activated Injection Site integrity after being equipped with artificially aged non-sterile stems.

**Background:**
Silicone stems were challenged by exposure to elevated temperature to achieve accelerated shelf life effects. The stem capability to accept standard MLL connectors after a certain shelf life was tested. Further, Robertsite valves equipped with aged non-sterile stems were tested for sealing performance. The stem slit opening was tested prior to the assembly welding or sterilization to simulate shelf life of the stem alone. The slit shall open upon access by a standard MLL connector after the specified shelf life. The naturally occurring silicon cross-linking or “knitting” shall not prevent the luer from opening the slit.

It is understood that artificially accelerated age testing only approximately duplicates the behavior of the product in a packaged and sterilized state, or after assembly with other components by an OEM, and therefore no representation or conclusion may be made predicting the shelf life behavior of the stem beyond the reported results of this testing. Determination of shelf life of the stem in assembly with the OEM product is at the sole responsibility of the OEM.

**Method:**
Production stem samples were placed in an oven. The oven was set to 60ºC temperature and maintained and monitored for duration of the test. A 2.6 week time period was selected as the equivalent to one (1) year shelf life. After the specified time limit equivalent of four (4) and five (5) years shelf life, the sample stems capability to accept a standard MLL connector was tested. The stem was positioned into a Robertsite test housing (allows assembly without welding) and the valve is accessed by a standard MLL luer connector conforming to the ISO 594-2 specification.

The acceptance criteria is that the slit opens within one (1) second or less after a completed access.

The sample stems were then removed from the test housing and assembled per production procedure. Resulting Robertsite valve samples were tested for back pressure sealing performance. Multiple accesses were performed with standard syringes, PC 3ml MLL and PP 10ml ML.

Each sample was fully activated 100 times alternating the MLL and ML syringes, so each sample was activated 50X by a MLL syringe and 50X by a ML syringe.
The back pressure test was performed twice, first after the assembly and second after the samples were accessed 100 times.

The acceptance criteria was that, the valve seals at a minimum of 30 psig back pressure.

Results:
All stem samples tested after four (4) and five (5) years of accelerated shelf life passed the MLL syringe access testing.

Assembled Robertsite valves containing artificially aged stems of four (4) and five (5) years passed back pressure testing.

The mean for valves after assembly, as well as, after 100 activations ranged from 47 to 48 psig. All samples fell within a +/- 3σ distribution.

Conclusion:
The Robertsite valves assembled per HRC procedures and equipped with non-sterile stems exposed to accelerated shelf life of up to five (5) years can be accessed by standard MLL connectors and after up to 100 accesses pass HRC specification for back pressure seal performance (30 psig minimum).

OEM use recommendation:
Determination of shelf life of the stem in assembly with the OEM product and after sterilization is at the sole responsibility of the OEM.

Clinical use recommendations:
Follow the manufacturer’s recommendations in the Instructions For Use.

Robertsite® is a trademark of Halkey-Roberts Corp. U.S. patent nos. US 6,651,956 and 6,089,541.

Important: All HRC Medical Components are shipped bulk, non-sterile, and are single patient use medical device components requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The buyer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life
Declaration of Conformity

Halkey-Roberts Swabable products are in conformity with the biocompatibility harmonized standard:

ISO 10993-1: 2003, Biological Evaluation of Medical Devices

Signed: [Signature]  Date: 2/22/2011

Gordon Hicks
QA/RA Director
Halkey-Roberts Corporation

GENERAL INFORMATION:

Halkey-Roberts Corporation
An Atrion Company
2700 Halkey-Roberts Place N.
Saint Petersburg, FL 33716

Phone: (727) 471-4200
Fax #: (727) 578-0450

Company Contacts:
David Battat, President
Jeff Strickland, Atrion CFO, HRC Vice President, Finance
Alan King, Vice President, Operations
Lew Lecceardone, Vice President, Medical Marketing/Customer Service
John Lucius, Vice President, Inflation Marketing/Product Development
Gordon Hicks, Director, Quality Assurance

Quality Certifications:
Scope of our ISO9001: The design, molding and assembly of Medical Valves, Inflation Valves and Pressure Relief Valves.
Scope of our ISO13485: The design, molding and assembly of Medical Valves and Medical Pressure Relief Valves.

FDA Information:
Registration Number: 1000324175
Owner/Operator Number: 9914015

Years in operation: 73
Facility type: 169,000 square feet
Size of work force: 270 employees, 3 shifts
Estimated turnover rate: 1%
Approx. number of customers: 500/600
Management Structure: Reference Organizational Chart (Attached)

COMPANY OVERVIEW:

Halkey-Roberts Corporation designs, develops, manufactures and sells products utilized in the inflation and medical device industry. Our products range from hand pumps to manual inflator valves in the inflation section to needle less and luer intravenous administration injection sites in the medical device section. Major international companies market and distribute our products to airline manufacturers, boating supply manufacturers for inflation products, to hospitals, clinics, surgical centers, physicians and other health care providers in the medical device products group.

Founded in 1941 in Paramus, New Jersey by Henry Mackal, HRC first manufactured screw machine parts primarily for the defense industry. HRC moved its headquarters and manufacturing operations to its present location in St. Petersburg, Florida in 1980. In 1996, Atrion Corporation acquired HRC.

Over 200 HRC people design, manufacture and test components for the medical device, medical component, inflation, and container industries at our 169,000 square foot St. Petersburg facility. Our products are manufactured on state-of-the-art equipment including 26 molding machines, 16 plastic and 3 silicone LIM – ranging in capacity from 40 to 400 tons. In addition, we have designed and built 24 automatic and semi-automatic precision assembly machines to provide our people with the best possible equipment to do their jobs.

Halkey-Roberts Corporation is committed to total customer satisfaction. That commitment is reflected in the fifty products we created or modified over the past three years in direct response to customer needs. It is also reflected in our proprietary testing machines capable of providing 100% product testing where necessary.

Halkey-Roberts Corporation will supply your company with products that provide value to your customers. We are dedicated to offering you on time delivery of the highest quality components that will meet your specific needs.
Organizational Chart Halkey-Roberts Corporation

CEO of Atrion

President of Halkey Roberts

Vice President Finance

Chief Technology Officer

*Director Quality Assurance

Vice President Inflation Marketing

Human Resources Manager

Vice President Medical Marketing

Customer Service

Vice President Operations & Product Development

Accounting

Info Systems Manager

Quality Engineer (QC)

Quality Engineer (QA)

Data Document Control Administrator

Sales Engineer

Customer Service

Purchasing

PPIC Manager

PPIC

Shipping and Receiving

Mgr Assembly Operations

Medical

Inflation

PRV

Manufacturing Engineering

Assembly Maintenance

Molding Manager

1st Shift

2nd Shift

3rd Shift

Maintenance Manager

Facility Maintenance

Product Development

Automation Engineering Group

Molding Maintenance

Tool Room

*Management Representative
Quality Management System

General Requirements
Halkey-Roberts, Corporation (“HR”) is a large volume manufacturer of bulk, non-sterile medical device components, general use Pressure Relief Valves and Inflation System Components.

Quality System Standards Applied
Halkey-Roberts Corporation’s Quality Assurance department has been delegated management responsibility for the effective deployment of the quality system, but Executive Management retains overall responsibility for establishing and enforcing quality policies. Processes for this system are found in appendix 1, page 23, titled “Processes and Resources Flowchart.

Regulatory Scope of HR products - As a manufacturer of bulk, non-sterile medical device components, HR is registered with FDA as a contract manufacturer. Shipment of medical device components to international locations does not require any specific regulatory activities at this time. All HRC medical device components are shipped and identified as requiring further processing (e.g. assembly, packaging, sterilization) before clinical use. The device manufacturer is responsible for determining effects of processing/multiple usage on these components, the appropriateness of the component in the final application, and pre/post shelf life.

The inflation products are subject to ISO 9001:2008 and specific performance standards related to Life Preserver components issued by the U.S. Federal Aviation Agency (FAA), Technical Standard Order, TSO-C13f, Life Preservers and the UL/ANSI 1191 Standard- Components for Personal Flotation Devices. HR is audited by both FAA and UL for compliance to these standards.

Documentation requirements
General Requirements - Documents and data affecting quality and supporting the quality system shall be controlled, including this Quality System Manual, Quality System Procedures, Work Instructions, drawings and, to extent applicable, documents of external origin such as standards and customer drawings.

Halkey-Roberts Corporation employs a three level documentation system:
- Level 2: Quality Management Procedures (QM’s). QM’s are under central document control and are maintained by Quality Assurance. QM’s shall cover the responsibilities delegation of authority, and specific departmental interrelations that are part of the quality system.
- Level 3: Standard Operating Procedures, drawings, Bills of Material, etc. These are controlled either centrally by Document Control for medical components (devices) or by the applicable department for non-medical items.

Control of documents - Document and Data Approval and Issue
- All applicable documents shall be reviewed and approved for adequacy by authorized personnel prior to use. A master list, or other equivalent method, shall be utilized and readily available to identify the current revision status of all documents to preclude usage of obsolete documents.
- All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.
- Changes or revisions to documents and data shall be identified, verified, and approved by the same department position(s) that approved the initial document, unless specifically designated otherwise.
- All controlled documentation will contain a change history that provides traceability to all previous revisions.
- Appropriate documents shall be available to all locations essential to the effective functioning of the quality system. The distribution system for documents, including the removal of obsolete documents, shall be specified.
- Uncontrolled documentation may be used for reference only, but shall not be used for manufacturing, test/inspection, or any work affecting quality.
- Obsolete documents are not to be used with the quality system, except in cases where required for previous revision product(s) being upgraded or a similar situation, and these shall be suitably identified.
- At least one copy of obsolete product-specific documents shall be retained to ensure that specifications to which devices have been manufactured are available for the lifetime of the product.

Control of records - Quality records are considered one of the principal forms of objective evidence of quality and shall be maintained to demonstrate achievement of the required quality and effective operation of the ISO 9001, ISO 13485, and QSR Regulations quality system. Procedures shall be established and maintained for the identification, collection, indexing, filing, storage, maintenance, retention period(s) and disposition of all quality records, including pertinent supplier records.

These procedures shall define the means of storage and maintenance of quality records to prevent loss and minimize deterioration or damage. Retention times shall be clearly defined in accordance with:
- Customer requirements;
- Regulatory requirements;
- Any Halkey-Roberts Corporation requirements as appropriate.

All required records pertaining to a medical device shall be retained for a period of time as designated in SOP requirements. Quality records shall be available to employees of the FDA designated to perform inspections and where agreed contractually for evaluation by the customer or customer representative for any previously defined and agreed period. Quality records may be hard copy, electronic per 21 CFR 11 impacts, or other media type.
Halkey-Roberts Corporation shall establish and maintain a record for each lot or batch of finished product that provides traceability to the extent required (see section 8 of this manual) and identifies the quantity manufactured and the quantity released for distribution. This record shall be verified and authorized.

Management Responsibility
Management Commitment - Halkey-Roberts executive management is committed to conforming to the stated Quality Management System standards as a means to ensure that the customers’ requirements are met in a timely manner and quality product is produced for all customers. The Quality Policy is established by HR Executive Management. All personnel are informed of the company’s commitment to quality and the Quality Policy through documented training. Periodic management reviews are held for executive management by the Management Representative according to the requirements in the SOP requirements.

Resources - Executive Management shall identify resource requirements and provide adequate resources, including the assignment of qualified and/or trained employees to ensure and verify product quality and the suitability and effectiveness of the quality system.
Process Control - Manufacturing shall plan the production processes that directly affect quality and ensure that these processes shall be carried out under controlled conditions. Change Control is a Central Document Control function.

Customer Focus - High quality and consistency in products, policies and service are our hallmark in all relationships with customers, suppliers and other members in the business community. All aspects of our business shall reflect the highest standards of dedication and ethics.

Executive Management shall ensure that customer requirements are determined through a systematic review of all customer inputs including but not limited to statutory and regulatory, customer specifications, drawings, purchase order and any other pertinent requirements determined by HRC. Executive Management shall ensure that customer requirements are met by monitoring information including but not limited to Customer Complaint Handling, Corrective and Preventive Action, Quality Audits (Internal and External) and yearly Customer Survey and as required by the Feedback Systems Procedure.

Contract Review - Executive Management shall review customer requirements prior to entering into a new ongoing contractual agreement per SOP requirements. Customer Services shall review subsequent production releases (customer purchase orders) to ensure the requirements are fully understood and Halkey-Roberts Corporation can meet the requirements.

Review - Each contract shall be reviewed for:
- Clear, well defined and documented requirements including design requirements developed by HRC engineering or the customer; for customer purchase orders where no written statement is available for an order received by verbal means, Customer Services shall ensure that the order requirements are agreed before their acceptance.
- The resolution of any requirements different from any previous agreements.
- The ability of our company to meet the requirements upon acceptance of a contract.
- Any ambiguities, mistakes or items needing clarification shall be referred back to the customer. In such cases, the customer shall be responsible to verify the requirements.

Amendment To Contract - Any amendment to an ongoing contract (not a customer purchase order) shall be reviewed and approved by Executive Management before being forwarded to Customer Services for appropriate action. Customer Services is responsible for changes to customer purchase orders and for correctly transferring the changes to functions concerned with the organization.

Records - Records of contract reviews shall be maintained.

Quality Policy - To design, manufacture and package products that satisfy our customers’ needs per required specifications, maintain an effective continually improving Quality Management System and products while complying with regulatory requirements.

The Quality Policy is controlled through the Quality System Manual. If it is changed, all Quality Policy postings throughout the company shall be updated. The Quality Policy shall be posted at visible locations throughout the company, and employees shall receive training to understand our Quality Policy.

Quality Planning - The three levels of the quality system documentation represent Halkey-Roberts Corporation’s quality plans. All products shall follow Quality System Procedures and Standard Operating Procedures from contract review to shipment. Halkey-Roberts Corporation shall develop plans for the manufacture and inspection and test of every product we develop.

Quality management system planning - Halkey-Roberts Corporation shall give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects, or contracts:
- The preparation of quality plans;
- The identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required quality;
- Ensuring the compatibility of the design, the production process, inspection, and test procedures, and the applicable documentation,
- The updating, as necessary, of quality control, inspection, and testing techniques, including the development of new instrumentation.
- The identification of any measurement requirement involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed;
- The identification of suitable verification at appropriate stages in the realization of product;
- The clarification of standards of acceptability for all features and requirements, including those that contain a subjective element;
- The identification and preparation of quality records;

Responsibility, authority and communication

Responsibility and authority - Executive management is responsible for appointing staff to ensure that the following requirements are met. Executive management is also responsible for ensuring an appropriate disaster management plan is in place to adequately all resources in emergency situations. All employees have the freedom and authority to initiate action to prevent the occurrence of nonconformities and identify and record any problems relating to product, process and quality system. In addition they can, through proper channels, recommend solutions and verify the implementation of solutions, reference section 14 of this manual. Manufacturing and Quality Assurance personnel are responsible for verifying product quality and controlling further processing or movement of nonconforming product until the condition is corrected.

Management Representative - The Director of Quality Assurance is the Management Representative of Halkey-Roberts Corporation. The Management Representative has the authority and responsibility for ensuring that requirements of ISO 9001: 2008 Quality System Standard; ISO 13485: 2003 Medical Devices – Quality management systems – Requirements and the U.S. FDA’s Quality System Regulation for medical devices (QSR) (21 CFR 820) are implemented and maintained. The Management Representative is also responsible for reporting on the performance of the quality system to Executive Management, as appropriate.

Internal Communication - The Management Representative is also responsible for reporting on the performance of the quality system to Executive Management, as appropriate and to insure that adequate internal communication takes place regarding the effectiveness of the quality management system.
Management Review

General – Executive Management shall conduct reviews of the quality system using internal and external feedback. Periodic limited monitoring should be conducted during the year per SOP along with yearly full reviews. The reviews consider topics such as the results of quality audits, resolution of customer complaints, and solutions to quality problems. The review shall be used for evaluating the continuing suitability and effectiveness of the quality system in satisfying the quality system requirements and the Quality Policy and objectives. Minutes of such reviews shall be documented and maintained by the Director of QA.

Review Input – The reviews consider topics such as the results of quality audits, resolution of customer complaints, and solutions to quality problems. The review shall be used for evaluating the continuing suitability and effectiveness of the quality system in satisfying the quality system requirements and the Quality Policy and objectives. Minutes of such reviews shall be documented and maintained by the Director of QA.

Review output – The outputs from the management review shall include any decisions and actions related to improvements needed to maintain the effectiveness of the quality management system, improvements of products and related customer requirements and resources needed.

Resource management

Provision of resources - HRC Management shall determine and provide the resources necessary to implement the quality management system, maintain its effectiveness, and meet regulatory and customer requirements.

Human resources

General – Halkey-Roberts Corporation ensures the proper allocation of financial and personnel resources necessary to maintain the effectiveness of the quality system through meetings involving executive management, including management reviews of the quality system. Such resources include trained and qualified personnel necessary to manage, perform work, verify product quality and conduct internal quality audits.

Competence, awareness and training -

- Each department manager or supervisor shall be ultimately responsible for identifying any training required for their employees.
- They shall ensure that all identified training has occurred.
- Employees performing specific assigned tasks shall be qualified on the basis of appropriate education, training, and/or experience as required for the particular function.
- As part of their training, employees shall be made aware of device defects that may occur from the improper performance of their specific jobs.
- Employees who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.
- All personnel who are required to work under special environmental conditions or who perform special processes or functions shall be appropriately trained or supervised by a trained person.

Infrastructure - Executive management shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable: buildings, workspace and associated utilities, process equipment (both hardware and software) and supporting services such as transport or communication.

Work Environment - As a manufacturer of medical valves, Halkey-Roberts maintains controlled environment for assembly of medical components and molding of select components. The environmental controls in place are intended solely for reduction of contaminants that may result in reduced yields in our final testing operations. Currently, there are no customer requirements in place that would indicate that the HRC product lines need environmental controls or indicate that the work environment can have an adverse effect on the quality of the end medical device using HRC components. HRC supplies only bulk non-sterile medical device components. There is no intention of maintaining a certification to any clean room standard at this time. Enforcement of our controlled environment practices is limited to our internal procedures only.

Product Realization

Planning of product realization - Executive management shall plan and develop the processes needed for product realization. Product realization planning shall be consistent with the requirements of the other processes of the quality management system. Planning shall determine the following: quality objectives and requirements for the product; need to establish processes, documents and provide resources specific to the product; required verification, validation, monitoring, inspection and test activities specific to the product and criteria for product acceptance; records needed to provide evidence that the realization processes and resulting product meet requirements. The output of this planning shall be documented per SOP requirements. A risk management program shall also be documented per SOP requirements.

Executive Management reviews customer requirements prior to entering into a new ongoing contractual agreement (Purchase Order/Agreement, Customer Drawings, and Customer Specifications) per SOP requirements. Customer Services shall review subsequent production releases (customer purchase orders) to ensure the requirements are fully understood and Halkey-Roberts Corporation can meet the requirements.

Amendment To Contract - Any amendment to an ongoing contract (not a customer purchase order) shall be reviewed and approved by Executive Management before being forwarded to Customer Services for appropriate action. Customer Services is responsible for changes to customer purchase orders and for correctly transferring the changes to functions concerned with the organization.

Records - Records of contract reviews shall be maintained.

Design and Development

Design and Development Planning - Design and development activities shall be planned and assigned to qualified personnel equipped with adequate resources. Design plans shall be updated as the design evolves.

Organizational and Technical Interfaces - Organizational and technical interfaces between different groups which input into the design process shall be defined and the necessary information documented, transmitted, and regularly reviewed.

Design and Development Input - Design input requirements including regulatory and safety requirements shall be identified and documented and reviewed for adequacy. Incomplete, ambiguous or conflicting requirements shall be resolved by the project steering committee with approval, as necessary, of the customer per SOP requirements. Design input shall take into consideration the results of any contract-review activities.

Design and Development Output - Design output shall be documented and expressed in terms of requirements, calculations, and analyses. Design output shall:
- Meet the design input requirements.
- Contain or reference acceptance criteria.
Conform to appropriate regulatory requirements. 
Identify those characteristics of the design that are crucial to the safe and proper functioning of the product. 
Include a review of design output documents.

Design and Development Review - Halkey-Roberts Corporation shall conduct formal design review meetings at appropriate stages of design per SOP requirements. Participants shall include representatives of all functions concerned with the design stage being reviewed. Records of such reviews shall be maintained.

Design and Development Verification - At appropriate stages of design, design verification shall be performed to ensure the design output meets design input requirements for that stage. Records shall be maintained for this verification including clinical investigations, where required. The design teams shall plan, establish, and document verification of the design by means of design control measures such as:
- Holding and recording design reviews.
- Undertaking qualification tests and demonstrations.
- Carrying out alternate calculations.
- Comparing the new design with a similar, proven design.
- Laboratory tests and market/focus panel reviews.
- Customer evaluation.
- Risk Analysis (FMEA)

Design and Development Validation - Design validation shall ensure that product conforms to the customer use (samples) or in house simulated use and will make use of models and/or prototypes as appropriate.

Control of Design and Development Changes

Design Control - Design activities shall ensure that specified requirements are met.

Design Changes - The design process shall include a means of documenting and controlling changes to approved design documents utilizing HRC's controlled document system. The responsible engineer shall approve all changes.

Design Transfer - Design transfer shall assure that the device design is correctly translated into production specifications from R&D to manufacturing.

Design History File - A design history file shall be established and maintained for FDA Class II or Class III medical devices designed by HRC meeting the FDA definition of “finished device,” 21 CFR §200.3 (f). The design history file shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of design control. Design records for other products will be kept in project files, etc.

Purchasing - Purchasing shall be responsible for ensuring that all components, manufacturing materials and services affecting quality conform to specified requirements, and are purchased only from approved sources.

Purchasing Process - Quality Assurance shall be responsible for the supplier assessment process and approval of suppliers. Records of approved suppliers shall be established and maintained. Quality Assurance shall be responsible for determining if on-site audits of potential and/or approved suppliers are necessary to assess their capabilities and quality systems. The suppliers may be selected based on validation of data they supply and/or past performance record. A receiving inspection system shall be utilized to further ensure that all purchased components conform to requirements.

Purchasing Information - Purchasing shall provide documentation to the supplier that clearly describes the product ordered including, where applicable, quality system policies, procedures, specifications, process requirements, inspection instructions, and other relevant technical data, and the title, number, and issue of the quality system standard to be applied. Purchasing shall review and approve purchasing documents for adequacy of specified requirements prior to release. To the extent required for traceability copies of relevant purchasing documents are retained.

Verification of purchased product

Verification at our Supplier's Premises - Where Halkey-Roberts Corporation proposes to verify purchased components, manufacturing materials, and/or services at the supplier's premises, verification arrangements shall be made with the supplier and the method of product release shall be specified in the purchasing documents.

Customer Verification of our Supplier's Product - When required by contract, the HRC customer shall be afforded the right to verify a supplier. Halkey-Roberts Corporation shall arrange for the customer's inspection and accompany the customer. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable parts.

Receiving Inspection and Testing - Halkey-Roberts Corporation shall ensure that systems are in place and maintained to ensure that incoming components are verified upon receipt (except in the circumstances described in 10.2.3) by QA. Verification shall be accomplished by at least one of the following methods:
- Visual inspection.
- Dimensional measurements.
- Certificate of Compliance (Analysis).
- Customer certification.
- Supplier certification.

The methods of inspection plan setup, establishing of appropriate verification method, and applicable records shall be defined by receiving inspection Work Instructions. Such Work Instructions take into consideration the amount of control exercised at the supplier's premises and the recorded evidence of conformance provided. Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to prevent release in the event of nonconformity to specified requirements are found.

Production and service provision - Quality Assurance shall ensure that all equipment and processes are appropriate and properly installed, maintained, and operated to continually meet specified requirements. Computer software is controlled per SOP requirements. Where the results of processes cannot be fully verified by subsequent inspection and testing of the product (such testing operations where 100% of the tested product is destroyed), those processes shall be validated.

Control of production and service provision

In-Process Inspection and Testing - Halkey-Roberts Corporation shall inspect and/or test the product as required by the documented Work Instructions available in all appropriate Quality Assurance and manufacturing areas. Quality Assurance shall verify that the specified requirements for the product are met. The required inspection and testing and records shall be detailed in documented procedures. In addition to Quality Assurance inspection, product may be inspected by manufacturing operators during the manufacturing process.
Final Inspection and Testing - Halkey-Roberts Corporation shall ensure that final inspection and testing is performed in accordance with established Work Instructions for approval and control. Product shall not be released until all specified inspection and/or tests have been performed successfully with evidence of conformance established per the DMR.

Inspection and Test Records - Halkey-Roberts Corporation shall maintain records that provide evidence that the product has been inspected and/or tested. These records shall show whether the product has passed or failed the inspection and/or testing according to defined acceptance criteria.

- Movement of product is restricted until documented requirements are met in regard to inspection and/or tests. Any nonconforming product shall be identified and, where possible, segregated from production.
- Where the product failed any inspection and/or test, the procedures for control of non-conforming product shall apply.
- Records shall identify the inspection authority responsible for the release of the product.

All medical devices shall have a final QA release based upon approval of the DHR for each lot.

Validation of processes for production and service provision - Process validation requirements, including associated equipment and personnel shall be specified. Records shall be maintained for qualified processes, equipment and personnel, as appropriate.

Identification and traceability - Halkey-Roberts Corporation shall establish documented procedures for identification and control of product from receipt and during all stages of storage, production, delivery, installation (if applicable) and packaging. Special markings required on purchased items shall be specified on drawings, purchase orders, or other applicable technical documents. Medical devices that have been authorized for return shall be identified and distinguished at all times from normal production. Traceability shall be defined and documented for unique identification of individual product or batches on a work order (BOM) basis. This identification shall be recorded.

Control of Customer property/Supplied Product - HRC designs, developments and manufacturers proprietary designs, therefore, the requirements of the QSR and ISO 13485 regarding elements related to customer property do not apply. As a provision for changes to this current practice, HRC has developed an SOP to provide for the following:

- Halkey-Roberts Corporation shall ensure that systems exist for the verification, storage, and maintenance of customer property. Any product that is damaged, lost, or is unsuitable for use shall be recorded and reported to the customer.
- Customer-supplied product shall be subject to the same controls that apply to purchased components throughout the quality system, unless the customer's contract specifies more stringent controls.
- Records shall be kept on verification of quality inspection results pertaining to customer-supplied product and feedback to the customer shall be performed.

Preservation of product: Handling, Storage, Packaging, Preservation and Delivery - Controls shall be maintained and documented for handling, storage, packaging, preservation, labeling and shipping in order to protect the quality of products and prevent damage or loss. Halkey-Roberts Corporation shall establish and maintain procedures for the control of product with limited shelf life or requiring special storage conditions when appropriate. Such special storage conditions shall be controlled and recorded.

Handling - Handling shall be performed in a manner that will reduce the chance of or prevent inadvertent damage to product(s). If appropriate, special provisions shall be made for the handling of used product in order to prevent contamination of other product, the manufacturing environment or employees.

Storage - Storage areas and stock rooms shall be designed to prevent damage or deterioration of product. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

Packaging - All products shall be controlled in regard to packing, packaging and labeling processes to the extent necessary to conform to specified requirements. Any deviations from approved packaging shall be formally authorized.

Delivery - Halkey-Roberts Corporation shall ensure through ASTM testing and proper packaging that the product quality is protected after final inspection and test.

Control of monitoring and measuring devices - Control of Inspection, Measuring and Test Equipment

Halkey-Roberts Corporation shall ensure that all measuring and test equipment affecting quality is calibrated, controlled and well maintained. All measuring and test equipment, whether owned by Halkey-Roberts Corporation or furnished by the employee or customer, shall be checked and calibrated by Quality Assurance before initial use and rechecked at documented intervals.

Where test software or comparative references such as test hardware are used as suitable forms of inspection, they shall be checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production and shall be rechecked at prescribed intervals. Halkey-Roberts Corporation shall establish the extent and frequency of such checks and maintain records as evidence of control.

- Control Procedure - Halkey-Roberts Corporation shall determine the measurements to be made and the accuracy required, and selects the appropriate inspection, measuring, and test equipment that is capable of the necessary accuracy and precision. Measurements to be made for inspection and testing and the required accuracy are given on drawings. Quality Assurance personnel shall select appropriate equipment capable of the required accuracy.
- All calibrated equipment shall be either traceable to a national standard or when no standard exists the basis for calibration shall be documented.
- Work Instructions shall define the method of calibration for each type of equipment.
- All measuring and test equipment used for a purpose affecting quality, such as measuring product, shall be clearly labeled indicating the calibration status and the due date for the next calibration. Measuring equipment used for reference only and not for a purpose affecting quality may be labeled inactive. Calibration is not required on inactive equipment.
- Calibration records shall record the gage number, location, and results of the calibration for each piece of measuring and test equipment.
- Halkey-Roberts Corporation shall assess and document the validity of previous inspection and test results when inspection, measuring, and test equipment is found to be out of calibration.
- Environmental conditions shall be suitable as required for the equipment calibrated.
- Handling, preservation, and storage of calibrated equipment shall be such that the accuracy is maintained. If a calibrated instrument is dropped or there is reason to believe it is out of calibration, Quality Assurance shall be notified immediately to calibrate the equipment.
- Unauthorized adjustments of calibrated equipment are prohibited.
- Where the availability of technical data pertaining to the measurement equipment is a specified requirement, such data shall be made available, when required by the customer or customer's representative, for verification that the measuring equipment is functionally adequate.
**Monitoring and measurement**

**Feedback** - Halkey-Roberts Corporation shall maintain a documented feedback system to provide early warning of quality problems and for input into the corrective and preventive action system. Where post marketing surveillance is a regulatory requirement, this surveillance shall form part of the feedback system. All feedback information, including reported customer complaints and returned product shall be documented, investigated, interpreted, collated and communicated in accordance with a defined procedure by a designated person. The feedback system shall be incorporated into management reviews. Additionally, Halkey-Roberts Corporation shall maintain a documented procedure for the issue of advisory notices and the recall of medical devices. This procedure shall be capable of being implemented at any time.

**Internal audit** - Quality system audits are recognized as a powerful tool in the execution, monitoring and refinement of the quality system. Halkey-Roberts Corporation shall carry out a well-planned and documented system of internal audits to verify the effectiveness of the quality system.

- Internal audits included in the audit program are system audits for verifying conformance to quality system requirements. In addition, process audits and product integrity audits shall be performed as deemed appropriate by the Director of Quality Assurance.
- Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited.
- Results of audit activities shall be documented and brought to the attention of the employee having responsibility in the area audited. Management of the area shall take timely corrective and/or preventive action on the findings of the audit.
- Audits shall be conducted by trained audit personnel. Results of audits shall be retained in audit reports in accordance with a Quality Records procedure. Audits shall be conducted by employees independent of the work being performed.
- Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.
- Audit reports and findings are considered confidential and can only be released outside the company through the written authorization of the designated RA for Halkey-Roberts Corporation.

**Monitoring and measurement processes**

**General** – Halkey-Roberts Corporation maintains quality plans to insure the monitoring, measurement, analysis and improvement processes needed. Manufacturing shall plan the production processes that directly affect quality and ensure that these processes shall be carried out under controlled conditions. Change Control is a Central Document Control function. The following measures assure controlled conditions:

- Documented procedures and/or other applicable documentation shall be in place and utilized in areas where their absence could adversely affect quality.
- Use of suitable production equipment and a suitable working environment including, to the extent necessary, environmental controls for products with special cleanliness requirements.
- Compliance with reference standards/codes and documented procedures.
- Processes and product characteristics shall be implemented and controlled following approval and prior to initiation of production.
- Equipment and/or tooling shall be evaluated, with performance capability demonstrated, as appropriate, prior to approval for use, to ensure that specifications can be met.
- Personnel shall be trained in processes, methods, and workmanship standards as applicable.
- Suitable maintenance of equipment to ensure continuing process capability. Where maintenance activities may affect product quality, Requirements for such activities shall be documented and records of the maintenance shall be kept.
- Requirements for health, cleanliness, and clothing of personnel if contact between such personnel and product or environment could adversely affect the quality of the product.
- Quality Assurance shall ensure that all equipment and processes are appropriate and properly installed, maintained, and operated to continually meet specified requirements. Computer software is controlled per SOP requirements.
- Where the results of processes cannot be fully verified by subsequent inspection and testing of the product (such as testing operations where 100% of the tested product is destroyed), those processes shall be validated.
- Process validation requirements, including associated equipment and personnel shall be specified.
- Records shall be maintained for qualified processes, equipment and personnel, as appropriate.
- Statistical methods for establishing, controlling and verifying activities include, but are not limited to, statistical sampling. Halkey-Roberts Corporation shall ensure sampling methods are regularly reviewed in the light of the occurrence of nonconforming product, quality audit results and other appropriate considerations. Statistical Techniques.
- Halkey-Roberts Corporation shall ensure identification and correct application of statistical techniques is applied as needed. Each department manager shall be responsible for identifying and implementing appropriate statistical techniques including any required by customer contract.
- If planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product per the requirements of SOP requirements.

**Monitoring and measurement of product**

**General** - Quality Assurance shall verify that the specified requirements for the product are met. The required inspection and testing and records shall be detailed in documented procedures. In addition to Quality Assurance inspection, product may be inspected by manufacturing operators during the manufacturing process.

**Receiving Inspection and Testing** - Halkey-Roberts Corporation shall ensure that systems are in place and maintained to ensure that incoming components are verified upon receipt by QA. Verification shall be accomplished by at least one of the following methods:

- Visual inspection
- Dimensional measurements
- Certificate of Compliance (Analysis)
- Customer certification
- Supplier certification.

The methods of inspection plan setup, establishing of appropriate verification method, and applicable records shall be defined by receiving inspection Work Instructions. Such Work Instructions take into consideration the amount of control exercised at the supplier's premises and the recorded evidence of conformance provided.

Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to prevent release in the event of nonconformity to specified requirements is found.

**In-Process Inspection and Testing** - Halkey-Roberts Corporation shall inspect and/or test the product as required by the documented Work Instructions available in all appropriate Quality Assurance and manufacturing areas. Movement of product is restricted until documented requirements are met in regard to inspection and/or tests. Any nonconforming product shall be identified and, where possible, segregated from production.
Final Inspection and Testing - Halkey-Roberts Corporation shall ensure that final inspection and testing is performed in accordance with established Work Instructions for approval and control. Product shall not be released until all specified inspection and/or tests have been performed successfully with evidence of conformance established per the DMR.

Inspection and Test Records - Halkey-Roberts Corporation shall maintain records that provide evidence that the product has been inspected and/or tested. These records shall show whether the product has passed or failed the inspection and/or testing according to defined acceptance criteria. Where the product failed any inspection and/or test, the procedures for control of nonconforming product shall apply. Records shall identify the inspection authority responsible for the release of the product. All medical devices shall have a final QA release based upon approval of the DHR for each lot.

Inspection and Test Status - Halkey-Roberts Corporation shall utilize methods such as stamps, tags, labels, physical location, and/or other suitable and effective means to indicate conformance or nonconformance to specified requirements.

- Product in between operations shall be in conformance based on release from the previous inspection.
- Any nonconforming product shall be suitably identified and the status must be apparent.

Control of nonconforming product - Halkey-Roberts Corporation shall take steps to identify, segregate, and disposition material and notify the functions concerned when nonconformity is detected. This shall apply to components and product in any stage of completion, including finished product. Nonconforming products shall be segregated from production and identified to prevent use until the disposition is complete.

Review and Disposition of Nonconforming Product - Halkey-Roberts Corporation shall ensure that nonconforming product is accepted only if specified or quality requirements are met but never if regulatory requirements are violated. Quality Assurance and other areas as appropriate shall be involved in making one of the following dispositions:

- Rework
- Accepted with or without repair by concession
- Deviate
- Return to source
- Scrap

Documented procedures on how to repair or rework nonconforming products shall be in place and a determination of any adverse effects will be established prior to taking the corrective action. Re-inspection shall be performed on all repaired or reworked material before further processing or use.

Analysis of data
In analyzing problems, investigation into product specifications, related processes, quality records, customer complaints, and other information shall be performed as necessary to help isolate the cause.

- All corrective and preventive action shall be to a degree appropriate to the magnitude of the problem and the likelihood of occurrence. Any changes to documented procedures resulting from corrective and preventive action shall be recorded.
- Corrective and preventive action does not exempt product(s) from meeting specified requirements. Halkey-Roberts Corporation shall maintain a documented feedback system to provide early warning of quality problems and for input into the corrective and preventive action system. Where post marketing surveillance is a regulatory requirement, this surveillance shall form part of the feedback system.
- All feedback information, including reported customer complaints and returned product shall be documented, investigated, interpreted, collated and communicated in accordance with a defined procedure by a designated person. The feedback system shall be incorporated into management reviews, reference section 1.3 of this manual.

Corrective action - Halkey-Roberts Corporation shall maintain a corrective and preventive action system for the purpose of eliminating root causes of detected problems related to material, manpower, and machines or written methods. Quality Assurance shall maintain a tracking system for assuring closure of all corrective action requests. Any Halkey-Roberts Corporation employee or customer may initiate corrective action requests. The system for corrective action shall include:

- The effective handling of customer complaints and reports of product nonconformities. If any customer complaint is not followed by corrective action, the reason shall be recorded.
- Investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation including notification of regulatory authorities per reporting criteria.
- Determination of the effectiveness of the corrective action.
- The establishment and maintenance of documented procedures for implementing corrective and preventive actions.
- Any corrective or preventative action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.
- The supplier shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

Preventive action - The system for preventive action shall include:

- The use of appropriate sources of information such as process and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze and eliminate potential causes of nonconformities.
- Determination of the steps needed to deal with any problems requiring preventive action.
- Initiation of preventive action and application of controls to ensure that it is effective.
- Confirmation that relevant information on actions taken is submitted for management review.

Customer Change Notification: HRC maintains a system of customer notification of HRC changes and will notify the customer of HRC changes involving new molds, material changes and characteristics that affect form function or fit or are identified on the customer source control print.
CERTIFICATE

This is to certify that

Halkey-Roberts Corp.
2700 Halkey-Roberts Place N
Saint Petersburg, FL 33716
United States of America

has implemented and maintains a Quality Management System.

Scope:
The design, molding and assembly of medical valves and medical pressure relief valves.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485: 2003

Certificate registration no. 10002437 MP23
Date of original certification 2005-12-27
Date of certification 2012-12-21
Valid until 2015-12-20

UL DQS Inc.

Ganesh Rao
Managing Director

Accredited Body: UL DQS Inc., 1130 West Lake Cook Road, Suite 340, Buffalo Grove, IL 60089 USA
CERTIFICATE

This is to certify that

Halkey-Roberts Corp.
2700 Halkey-Roberts Place N
Saint Petersburg, FL 33716
United States of America

has implemented and maintains a Quality Management System.

Scope:
The design, molding and assembly of medical valves, inflation valves and pressure relief valves.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001: 2008

Certificate registration no. 10002437 QM08
Date of original certification 2003-11-17
Date of certification 2012-12-21
Valid until 2015-12-20

UL DQS Inc.

Ganesh Rao
Managing Director

Accredited Body: UL DQS Inc., 1130 West Lake Cook Road, Suite 340, Buffalo Grove, IL 60089 USA