Instructions for Use

RADIOFREQUENCY PROBE & RADIOFREQUENCY GENERATOR CONNECTOR CABLE
Fig. 1  PMX-XX-YYC

Fig. 2  PMX-BAY-BAY

Fig. 3  PMX-RAD-BAY

Fig. 4  PMX-BAY-ORA

Fig. 5  PMX-NEU-BAY

Fig. 6  PMX-SAC-BAY

[Non-Pyrogenic] [Rx Only] [Caution] [Consult instructions for use] [Dispose of properly]
**Device Description**

The HALYARD® Radiofrequency (RF) Probes (Fig. 1) are individual electrodes that are used with a disposable radiofrequency (RF) cannula (sold separately) of the corresponding gauge and length. The HALYARD® Radiofrequency (RF) Generator Connector Cables (PMX-BAY-BAY (Fig. 2), PMX-RAD-BAY (Fig. 3), PMX-BAY-ORA (Fig. 4), PMX-BAY-NEU (Fig. 5) and PMX-SAC-BAY (Fig. 6)) respectively connect the HALYARD® RF Probes to the RF Generator, connect the HALYARD® RF Probes to the Valleylab® RFG Series Generator, connect the HALYARD® RF Probes to the Neurotherm® Generator, connect the HALYARD® RF Generator (formerly Kimweili-Clark® RF Generator or Baylis Pain Management Generator) to the Smith & Nephew® Probe Model: 4-Pin Intradiscal Catheter, 4-Pin Intradiscal Catheter XL or 4-Pin Intradiscal Decompression Catheter, connect the HALYARD® RF Probes to the STRYKER® RF Generator cable or STRYKER® RF Multi-Gen Cable.

**Indications For Use**

HALYARD® Radiofrequency Probe and HALYARD® Radiofrequency Generator Connector Cable will be used in conjunction with a radiofrequency generator to create lesions in nervous tissue.

**Contraindications**

For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position.

This procedure should be reconsidered in patients with any prior neurological deficit.

The use of general anesthesia is contraindicated. To allow for patient feedback and response during the procedure, treatment should be performed under local anesthesia.

Systemic infection or local infection in area of the procedure.

Blood coagulation disorders or anticoagulant use.

**Warnings**

- The HALYARD® RF Probes and RF Generator Connector Cables are shipped non-sterile and must be cleaned and sterilized prior to use as instructed in the Instructions for Use.

- The HALYARD® RF Probes and RF Generator Connector Cables are reusable devices. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.

- The HALYARD® RF Probes and RF Generator Connector Cables must be used with the correct connector cable. Attempts to use it with other RF Generator Connector Cables can result in electrocution of the patient or operator.

- Laboratory staff and patients can undergo significant x-ray exposure during RF procedures due to the continuous use of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.

- Discontinue use if inaccurate, erratic or sluggish temperature readings are observed. Use of damaged equipment may cause patient injury.

- Do not modify HALYARD® Equipment. Any modifications may compromise the safety and efficacy of the device.

- When an RF Generator is activated, the conducted and radiated electrical fields may interfere with other electrical medical equipment.

- The RF Generator is capable of delivering significant electrical power. Patient or operator injury can result from improper handling of the RF Probe, particularly when operating the device.

**Adverse Events**

Potential complications associated with the use of this device include but are not limited to: infection, nerve damage, increased pain, visceral injury, failure of technique, paralysis, and death.

**Product Specifications**

The HALYARD® RF Probes should be used by physicians familiar with RF lesion techniques.

**HALYARD® RF Probe (Fig. 1)**

The HALYARD® RF Probes (PMP) are individual electrodes that are used with disposable RF cannula (sold separately) of the corresponding gauge and length.

- Available with straight and curved cannulae.

- Model number indicates cannula information.

- Model Number Probe-XX-YYC, where:
  - XX: indicates length of cannula associated with the probe
  - YY: indicates gauge of cannula associated with the probe
  - C: if present, indicates that cannula is curved.

**Note:** Please contact Halyard Health for a list of all model numbers and sizes.

- RF Probes are shipped non-sterile and must be sterilized as per Instructions for Use prior to use.

- Are supplied non-pyrogenic.

- Are supplied with the following additional parts:
  - protective tubing, to prevent bending or kinking of the RF Electrode during handling.

- Black 4-pin, male connector (Probe Plug-In) to connect the HALYARD® RF Probe to the RF Generator Connector Cable.

- Color-coded bend relief which corresponds to the gauge of the cannula they should be used with:
  - White = 16G
  - Pink = 18G
  - Yellow = 20G
  - Green = 21G
  - Black = 22G

- Black probe cable for use with straight cannula and a white probe cable for use with curved cannula.

**Storage Instructions**

- HALYARD® RF Probes should be stored in a cool, dry place.

- Store the RF Probes in the Sterilization and Storage Tray provided to reduce the risk of damage due to storage.
Special Handling Instructions

The HALYARD* RF Probe is delicate due to its small diameter RF electrode. Do not bend, kink, or stress the RF electrode. Do not crush or splice the probe cable. Doing so could damage the temperature sensing mechanism in the device and lead to improper temperature measurement.

HALYARD* RF Generator Connector Cables

- Five models (PMX-BAY-BAY, PMX-RAD-BAY, PMX-BAY-ORA, PMX-NEU-BAY, PMX-SAC-BAY)
- Shipped non-sterile and must be sterilized as per User's Manual prior to first use.

PMX-BAY-BAY (Fig. 2)

The HALYARD* PMX-BAY-BAY connects the HALYARD* RF Probe to the Generator (PMG).
- Two different connectors:
  1. 4-pin female – RF Probe Connector (to connect to Probe)
  2. 14-pin male – RF Generator Plug-In (to connect to Generator)

PMX-RAD-BAY (Fig. 3)

The HALYARD* PMX-RAD-BAY connects the HALYARD* RF Probe (PMP) to a Valleylab® RFG Series Generator.
- Two different connectors:
  1. 4-pin female – RF Probe Connector (to connect to Probe)
  2. 14-pin male – RF Generator Plug-In (to connect to Generator)

PMX-BAY-ORA (Fig. 4)

The HALYARD* PMX-BAY-ORA connects the HALYARD* RF Generator to the Smith & Nephew Probe Model: 4-Pin Intradiscal Catheter or 4-Pin Intradiscal Catheter XL.
- Two different connectors:
  1. 4-pin female – RF Probe Connector (to connect to Probe)
  2. 14-pin male – RF Generator Plug-In (to connect to Generator)

Note: Cable should NOT be used with the Intradiscal decompression catheter if the generator in use is Generator Version 1.2 or lower.

Note: If using the PMG Version 2.0, ensure that the secondary thermocouple option is disabled. Refer to Generator-TD User Manual.

- Are used to connect an IDL probe (model 902002) to the HALYARD* RF Generator.
- Should NOT be used with the IDL decompression catheter if the generator in use is PMG Version 1.2 or lower.
- Have two different connectors:
  1. 4-pin female – RF Probe Connector (to connect to Probe)
  2. 14-pin male – RF Generator Plug-In (to connect to Generator)

PMX-NEU-BAY (Fig. 5)

The HALYARD* PMX-NEU-BAY connects the HALYARD* RF Probes to the Neurotherm* Generator.
- Two different connectors:
  1. 4-pin female – RF Probe Connector (to connect to Probe)
  2. 4-pin male (metal) – RF Generator Plug-In (to connect to Generator)

PMX-SAC-BAY (Fig. 6)

The HALYARD* PMX-SAC-BAY connects the HALYARD* RF Probes to the STRYKER® RF Generator or STRYKER® RF Multi-Gen.
- Two different connectors:
  1. 4-pin female - RF Probe Connector (to connect to Probe)
  2. 12-pin male (metal) - RF Generator Plug-In (to connect to Generator cable)

Storage Instructions

- HALYARD* RF Generator Connector Cables should be stored in a cool, dry place.
- Store the RF Generator Connector Cables in the Sterilization and Storage Tray provided to reduce the risk of damage due to storage.

Autoclave Case is:

- Shipped non-sterile.
- Should be used at all times to store the HALYARD* Probe and HALYARD* RF Generator Connector Cable.
- Steam sterilizable and should be used to hold the devices while they are being sterilized.
- NOT to be used with STERRAD*.

Inspection Prior to Use

Perform the following checks before the patient is presented for the procedure. These steps will allow you to verify that the equipment you will use is in proper working order. Do these tests in a sterile environment.

- Sterility Check: The HALYARD* RF Probes and RF Generator Connector Cables are shipped non-sterile. They must be sterilized prior to each use.
- Visual Inspection: Ensure RF Probes and RF Generator Connector Cables have no visible damage such as discoloration, cracks, label fading, cable splice, or kinks. Do NOT use damaged or defective equipment.
- Residual Moisture: Ensure the RF Probes and RF Generator Connector Cables are dry. Residual moisture can cause malfunctions.

Equipment Required

RF lesion procedures should be performed in a specialized clinical setting with fluoroscopic equipment. The RF equipment required for the procedure is as follows:
- Disposable RF Cannula
- RF Probe and corresponding RF Generator Connector Cable
- RF Generator
- Disposable Indifferent (dispersive) Patch (DIP) electrode meeting ANSI/AAMI standard HF-18 requirements for electrosurgical electrodes.

Instructions for Use

1. Assemble all required equipment for the intended procedure and position the patient as necessary.
2. Attach the Disposable Indifferent (dispersive) Patch (DIP) electrode. Read and follow the manufacturer's Instructions for Use of the (DIP) electrode to determine proper placement. Always use DIP electrodes that meet or exceed ANSI/AAMI HF-18 requirements.
3. Connect the appropriate connector cable to the connector cable connection on the RF generator. Maintain access to the RF Probe Connector on the connector cable in order to facilitate easy attachment of the probe.
4. With the stylet in the cannula, insert the cannula into the patient using fluoroscopic guidance to place the active tip at the desired lesion location.
5. Once the cannula is properly placed, carefully remove the stylet from the cannula and insert the (pre-sized) RF Electrode down the shaft of the cannula.
6. Attach the probe to the connector cable (via the Probe Plug-In and RF Probe Connector).
7. Stimulate and lesion as necessary. Refer to the RF Generator User's Manual for more information.

After the Procedure

1. Remove RF electrode of the probe from the cannula.
2. Remove cannula from the patient.
3. Disconnect the RF Probe from the RF Generator Connector Cable by pulling on the plug body.

Caution: Prevent damage to your cable and probe. When pulling the connectors apart be sure to pull on the plug and not the cable.
4. Disconnect the RF Generator Connector Cable from the generator.
5. Discard the cannula.
6. Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from patient and discard.
7. Prepare the reusable probe and connector cable for cleaning and sterilization. Transfer the used HALYARD* RF Probe and HALYARD* RF Generator Connector Cable to a carrying surface and cover them with a wet cloth to ensure that blood and other contaminants do not dry on the surface.

Cleaning and Sterilization Instructions

Danger

The HALYARD* RF Probe and HALYARD* RF Generator Connector Cable are shipped non-sterile and must be cleaned and sterilized as per these instructions for Use prior to each use. Failure to properly clean and sterilize the device can cause patient injury and/or the communication of infectious diseases from one patient to another.
**Important**
The manufacturer recommends the user follow a quality control program for each sterilization cycle that meets or exceeds American Operating Room Nurses (AORN) Standards, Recommended Practices & Guidelines - 2000. This program includes, but is not limited to recording:
- Type of sterilizer and cycle used
- Lot control number
- Load contents
- Exposure time and temperature, if not provided by a recording chart
- Operator’s name
- Results of sterilization process monitoring (i.e., chemical, mechanical, biological)

**Cleaning and Decontamination**

1. Ensure that blood and other contaminants do not dry on the HALYARD* RF Probe and the HALYARD* RF Generator Connector Cable. 
2. Remove the protective tube from the probe and follow the Instructions below for each piece separately.
3. Rinse all parts with deionized water until colorless run-off water occurs. Once the water runs clear soak the parts (except for the connectors) in deionized water at 22°C-48°C for 1 minute. Remove the probe and components from the water and scrub them with a soft bristle brush until they are visually clean. **Note:** Do not let the connectors soak. Wipe connectors as necessary until they are visually clean.
4. Soak the probe and components (except connectors) in an enzymatic cleaning solution for 20 minutes. Ensure that the temperature of the solution is below 55°C. Scrub again with a soft bristle brush, and rinse thoroughly using deionized water until all traces of detergent residue are removed.
5. Visually inspect the parts again for debris, if any is present repeat steps 3 and 4.
6. Dry the surface of the device on the outside with a clean, dry towel. Put the protective tube back onto the probe and place all parts back in the Sterilization and Storage Tray.

**Sterilization (ALL EXCEPT PMX-SAC-BAY)**
The following sterilization methods have been validated for use with HALYARD* RF Probes and RF Generator Connector Cables:
- Steam Sterilization
- Gravity Displacement Steam Sterilization
- STERRAD* Sterilization

**Sterilization (PMX-SAC-BAY)**
The following sterilization methods have been validated for use with HALYARD* PMX-SAC-BAY Generator Connector Cable:
- Steam Sterilization
- Gravity Displacement Steam Sterilization

**Steam Sterilization**
Prevaccum: Wrapped: 132°C-135°C (270°F-275°F) for 3-4 min.
Unwrapped: “Flash” 132°C for 4 min.

**Gravity Displacement Steam Sterilization**
Wrapped: 132°C-135°C (270°F-275°F) for 15 minutes
Unwrapped: “Flash” 132°C-135°C for 15 minutes

**STERRAD® Sterilization**
HALYARD* RF Probes and RF Generator Connector Cables may be sterilized with the following STERRAD® systems:
- STERRAD® 100S
- STERRAD® 50
- STERRAD® 200
- STERRAD NX®
- STERRAD 100NX

All instructions given in the corresponding STERRAD® Sterilization System User’s Guide must be followed.

**Note:** The HALYARD* RF Probe and RF Generator Connector Cable should NOT be sterilized within the autoclave case. Any validated tray recommended for use with STERRAD® may be used.

**Note:** For effective sterilization, the protective tube MUST be removed during sterilization and placed next to the probe in the tray.

### Warning
Halyard Health has validated ONLY the previously mentioned cleaning and sterilization methods for the HALYARD* RF Probe and HALYARD* RF Generator Connector Cable. No other cleaning and sterilization methods have been tested. If any other type of cleaning or sterilization method is used on these products, it is up to the user to verify sterility. Failure to properly clean the device can lead to patient injury.

**Troubleshooting**
The following table is provided to assist the user in diagnosing potential problems.

<table>
<thead>
<tr>
<th>PROBLEM</th>
<th>COMMENTS</th>
<th>TROUBLESHOOTING</th>
</tr>
</thead>
</table>
| No temperature measurement in treatment mode OR Inaccurate, erratic, or sluggish temperature reading in treatment mode | In order to measure temperature the entire system must be connected and all devices must be in good working order. | Ensure that all connections are made:  
  - probe to connector cable  
  - connector cable to generator  
  - generator to power outlet  
  Check for an error message on the generator.  
  Visually inspect the probe or cable for damage. Ensure that devices are dry and at room temperature. If problem persists, discontinue use. |
| RF Probe does not fit into the RF Cannula                              | The fit of the probe in the cannula is very precise. In very rare situations the manufacturing of the probe and/or cannula may prohibit the correct fit. | Ensure that the styllet has been removed from the cannula.  
  Ensure that the RF Electrode is completely smooth and clean.  
  Check the gauge of the cannula and ensure that the correctly sized probe is in use.  
  Try another cannula of the same size. |
| RF Probe Connector does not fit in RF Probe Plug-In                    | Each of the connectors is designed to connect in a specific way for safety reasons. If the connector “keys” are out of line the connectors won’t fit together. | Check that the connector’s keys are lined up in the proper orientation.  
  Ensure that the connectors are clean and unobstructed. |
| RF Electrode Breaks or Kinks                                           | Due to the small diameter shaft, the RF Electrode portion of the HALYARD* RF Probe can withstand very little damage due to handling. | Discard Immediately. |

**Customer Service and Product Return Information**
If you have any problems with or questions about this HALYARD* Equipment, contact our technical support personnel:
Halyard Health
5405 Windward Parkway
Alpharetta, GA 30004 USA
E-mail: PMPorders@hyh.com
1-844-425-9273 (1-844-HAL YARD)

**Notes**
In order to return products under limited warranty you must have a return authorization number before shipping the products back to Halyard Health.

**Limited Warranty**
Halyard Health warrants that these products are free from defects in original workmanship and materials. If these products prove to be defective in original workmanship or original materials, Halyard Health, in its absolute and sole discretion, will replace or repair any such product, less charges for transportation and labor costs incidental to inspection, removal or restocking of product.
This limited warranty applies only to original factory delivered products that have been used for their normal and intended uses. Halyard Health’s limited warranty shall NOT apply to Halyard Health’s products which have been repaired, altered or modified in any way and shall NOT apply to Halyard Health’s products which have been improperly stored or improperly installed, operated or maintained contrary to Halyard Health’s Instructions. The warranty period for HALYARD® RF Probe and RF Generator Connector Cables is 90 days from the date of purchase, unless otherwise stated.

Disclaimer and Exclusion of Other Warranties
There are no warranties of any kind, which extend beyond the description of the warranties as previously mentioned. Halyard Health disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use or purpose.

Limitation of Liability for Damages
In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Halyard Health shall not be liable for damages for loss of profits or claims of buyer’s customers for any such damages. Halyard Health’s sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Halyard Health to buyer which give rise to the claim for liability.

The buyer’s use of this product shall be deemed acceptance of the terms and conditions of these limited warranties, exclusions, disclaimers and limitations of liability for money damages.
The warranty period for Halyard RF Nitinol Probe and RF Generator Connector Cables is 90 days from the date of purchase, unless otherwise stated.

Disclaimer and Exclusion of Other Warranties

There are no warranties of any kind, which extend beyond the description of the warranties as previously mentioned. Halyard Health disclaims and excludes all warranties, whether expressed or implied, of merchantability or fitness for a particular use or purpose.

Limitation of Liability for Damages

In any claim or lawsuit for damages arising from alleged breach of warranty, breach of contract, negligence, product liability or any other legal or equitable theory, the buyer specifically agrees that Halyard Health shall not be liable for damages for loss of profits or claims of buyer's customers for any such damages. Halyard Health's sole liability for damages shall be limited to the cost to buyer of the specified goods sold by Halyard Health to buyer which give rise to the claim.

In any claim of personal injury or property damage arising from any cause, Halyard Health's liabilities shall be limited to the cost to buyer of the specified goods sold by Halyard Health to buyer which give rise to the claim.
### Troubleshooting

#### Problem

**Inaccurate** temperature measurement

**Sluggish** reading in treatment OR

**Erratic or** temperature measurement

#### Comment

#### Troubleshooting

The following table is provided to assist the user in diagnosing potential problems and finding solutions.

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<td>Inaccurate temperature measurement</td>
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</tr>
<tr>
<td>Erratic or temperature measurement</td>
<td>The following table is provided to assist the user in diagnosing potential problems and finding solutions.</td>
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</tbody>
</table>

#### Notes

- In order to measure temperature, a probe must be connected and all connections must be connected and all connectors won't fit into the generating connector.

#### Cleaning and Decontamination

The following procedures should be used to clean and decontaminate the HAL YARD RF Nitinol Probes and RF Generator Connector Cables.

<table>
<thead>
<tr>
<th>Cleaning and Decontamination Procedure</th>
<th>Method</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Wipe the probe and device with a clean, dry towel.</td>
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<tr>
<td>2. Remove the protective tube from the probe and follow the Instructions for cleaning and decontamination.</td>
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<tr>
<td>3. Rinse all parts with deionized water until colorless run-off water occurs.</td>
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<tr>
<td>4. Soak the probe and components (except connectors) in an enzymatic cleaning solution for 20 minutes.</td>
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<tr>
<td>5. Visually inspect the parts again for debris, if any is present repeat steps 3 and 4.</td>
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<td></td>
</tr>
<tr>
<td>6. Dry the surface of the device on the outside with a clean, dry towel.</td>
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<td></td>
</tr>
</tbody>
</table>

#### STERRAD® Sterilization

The following STERRAD® systems have been validated for use with the HAL YARD RF Nitinol Probes and RF Generator Connector Cables.

- STERRAD® 100S
- STERRAD® 50
- STERRAD® 200

#### Sterilization (Except PAR-VA®)

The following sterilization methods have been validated for use with the HAL YARD RF Nitinol Probes and RF Generator Connector Cables.

- Steam Sterilization
  - Vacuum: 132°C–135°C (270°F-275°F) for 3–4 minutes
  - Unwrapped: Flash 132°C for 4 minutes
- Gravity Displacement Steam Sterilization
  - Vacuum: 132°C–135°C (270°F-275°F) for 15 minutes
  - Unwrapped: Flash 132°C–135°C for 15 minutes
- STERRAD® Sterilization
  - Vacuum: 132°C–135°C (270°F-275°F) for 15 minutes
  - Unwrapped: Flash 132°C–135°C for 15 minutes

#### Limited Warnings

- RF Nitinol Probes and RF Generator Connector Cables may be sterilized in the following sterilization methods:
  - Steam Sterilization
  - Gravity Displacement Steam Sterilization
  - STERRAD® Sterilization

Note:

- The HAL YARD RF Nitinol Probe and RF Generator Connector Cable should not be connected and all connections must be connected and all connectors won't fit into the generating connector.

#### Customer Service and Product Return Information

If you have any problems with or questions about this HAL YARD Equipment, contact our technical support personnel:

- Halyard Health
- 5405 Windward Parkway
- E-mail: PMPorders@hyh.com

#### Limited Warranties

Halyard Health warrants that these products are free from defects in original materials and workmanship for the period specified below, subject to the terms and conditions set forth herein.

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#### Warranty Information

- This limited warranty applies only to original factory delivered products that are made and sold by Halyard Health.
- This limited warranty shall not apply to any such product that is modified, repaired, altered or used in any way not consistent with the intended use of the product.

#### Notes

- In order to return products under limited warranty you must have a return authorization number issued by Halyard Health.
- For effective sterilization, the protective tube MUST be removed during sterilization and placed next to the probe in the tray.

Note:

- The HAL YARD RF Nitinol Probe and RF Generator Connector Cables may be sterilized with STERRAD® systems.

Note:

- For effective sterilization, the protective tube MUST be removed during sterilization and placed next to the probe in the tray.

Note:

- The HAL YARD RF Nitinol Probe and RF Generator Connector Cables may be sterilized with STERRAD® systems.

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- The HAL YARD RF Nitinol Probe and RF Generator Connector Cables may be sterilized with STERRAD® systems.
**Preparation of the Equipment**

- **For RF Generator Connector Cables**:
  - **HAL YARD** RF Generator Connector Cables are shipped non-sterile and must be cleaned and sterilized as per User’s Manual prior to each use. Failure to properly clean and sterilize the device can cause patient injury and/or the transmission of infectious diseases from one patient to another.

- **For RF Nitinol Probe** and **HALYARD RF Generator Connector**:
  - These are shipped non-sterile. They must be cleaned and sterilized as per User’s Manual prior to each use.

**Equipment Required**

- **RF Nitinol Probe and corresponding RF Generator Connector Cable**
- **RF Generator**
- **Disposable Indifferent (dispersive) Patch (DIP) electrode meeting ANSI/AAMI HF-18 requirements**
- **Fluoroscopic equipment**
- **Equipment for the intended procedure** (e.g., PMG Version 1.2 or lower)

**Important**

- The manufacturer recommends the user follow a quality control program for recording sterilization information that meets or exceeds American Operating Room Nurses (AORN) Standards, Recommended Practices & Guidelines - 2000. This program includes, but is not limited to recording:
  - Lot control number
  - Load contents
  - Exposure time and temperature, if not provided by a recording chart

**Danger**

- Do not use damaged or defective equipment.

**Cleaning and Sterilization Instructions**

After the Procedure

1. Examine all equipment and components. If any are damaged, replace them.
2. Wash all metal components with a wet cloth to ensure that blood and other contaminants do not dry on the surface.
3. Remove RF Nitinol Probe of the probe from the cannula.
4. Ensure RF Nitinol Probes and RF Generator Connector cable splice, or kinks. Do NOT use damaged or defective equipment.
5. Disconnect the RF Nitinol Probe from the RF Generator Connector Cable.
6. Disconnect the RF Generator Connector Cable from the generator.
7. Discard the cannula.
8. Remove Disposable Indifferent (dispersive) Patch (DIP) electrode from the patient and discard.
9. Prepare the reusable probe and connector cable for cleaning and sterilization as per the manufacturer’s instructions.

**Storage Instructions**

- **HALYARD RF Generator Connector Cables** should be stored in a cool, dry place.
- **HALYARD RF Nitinol Probes** should be stored in a sterile environment.

**Troubleshooting**

- **HAL YARD** RF Generator Connector Cables are available in the following models:
  - **PMX-BAY-BAY**
  - **PMX-RAD-BAY**
  - **PMX-BAY-ORA**
  - **PMX-NEU-BAY**
  - **PMX-SAC-BAY**

**Procedures**

1. **Assemble all required equipment for the intended procedure and position the patient as necessary.**
2. **Attach the Disposable Indifferent (dispersive) Patch (DIP) electrode.** **Read** the manufacturer’s instructions for use of the (DIP) electrode. **Always use DIP electrodes** that meet or exceed ANSI/AAMI HF-18 requirements.
3. **Connect the appropriate connector cable to the connector cable (via the Probe Plug-In and RF Generator Connector).** **Note:** PMX-SAC-BAY...
4. **Prepare Nitinol Probe to the Nitinol Probe Connector.** **Note:** PMX-SAC-BAY...
5. **Remove RF electrode of the probe from the cannula.** **Note:** PMX-SAC-BAY...
6. **Attach the probe to the connector cable (via the Probe Plug-In and RF Generator Connector).** **Note:** PMX-SAC-BAY...
7. **Stimulate and lesion as necessary.** **Refer to the RF Generator User’s Manual.** **Additional information can be found in the manufacturer’s documentation.**

**Important**

- **Visual Inspection:**
  - **Equipment:** Inspect the equipment before use with the fluoroscopic equipment. The RF equipment required for the procedure is as follows:
    - **RF Nitinol Probe and corresponding RF Generator Connector Cable**
    - **RF Generator**
    - **Disposable Indifferent (dispersive) Patch (DIP) electrode**

- **RF Nitinol Probe and corresponding RF Generator Connector Cable**:
  - **1. 4-pin female – RF Probe Connector (to connect to Probe)**
  - **2. 4-pin male (metal) – RF Generator Plug-In (to connect to Generator)**
  - **1. 4-pin female – RF Probe Connector (to connect to Probe)**
  - **2. 14-pin male – RF Generator Plug-In (to connect to Generator)**

- **HAL YARD** RF Nitinol Probes and RF Generator Connector Cables are available in the following models:
  - **PMX-BAY-BAY**
  - **PMX-RAD-BAY**
  - **PMX-BAY-ORA**
  - **PMX-NEU-BAY**
  - **PMX-SAC-BAY**

- **RF Nitinol Probe Connector (BAY)**
  - **1. 4-pin female – RF Probe Connector (to connect to Probe)**
  - **2. 14-pin male – RF Generator Plug-In (to connect to Generator)**
  - **HAL YARD** RF Nitinol Probes and RF Generator Connector Cables are available in the following models:
    - **PMX-BAY-BAY**
    - **PMX-RAD-BAY**
    - **PMX-BAY-ORA**
    - **PMX-NEU-BAY**
    - **PMX-SAC-BAY**

**Safety Precautions**

- **RF Generator Connector Cables** should be stored in a cool, dry place.
- **HAL YARD** RF Nitinol Probes should be stored in a sterile environment.

**Emergency**

- **NOT to be used with STRYKER® RF Generator or STRYKER® RF Multi-Gen.**
- **NOT to be used with STERRAD®.**
HALYARD* RF Nitinol Probe (Fig. 1)

Are supplied non-pyrogenic.

Are supplied with the following additional parts:
- Protective tubing, to prevent bending or kinking of the RF electrode or 2) power failure to an electrical lead. Do not adjust treatment at normal settings may indicate: 1) faulty application of the dispersive electrode or 2) an electrical lead failure. Do not attempt to use the HALYARD* RF Nitinol Probes and RF Generator Connector Cables before thoroughly reading the Instructions for Use and the User’s Manual for the RF Generator.

Contraindications

For patients with cardiac pacemakers, a variety of changes can occur during and after the treatment. In sensing mode the pacemaker may interpret the RF signal as a heartbeat and may fail to pace the heart. Contact the pacemaker company and check with the manufacturer to determine if the stimulator needs to be in the bipolar stimulation mode or in the OFF position.

Radiofrequency Nitinol Probe & Radiofrequency Generator Connector Cable

The HALYARD* RF Nitinol Probes and RF Generator Connector Cables should be used by physicians familiar with RF lesion procedure. Each individual patient all foreseeable risks of the RF lesion procedure. Precautions

• Do not attempt to use the HALYARD* RF Nitinol Probes and RF Generator Connector Cables with RF equipment other than the Valleylab® RFG Series Generator, connect the HAL YARD* RF Nitinol Probes to the Valleylab® RFG Series Generator, connect the HAL YARD* RF Nitinol Probes to the Neurotherm® Generator, connect the HAL YARD* RF Nitinol Probes to the STRYKER® RF Generator cable or 4-Pin Intradiscal Catheter XL or 4-Pin Intradiscal Decompression Catheter, connect the HAL YARD* RF Generator (formerly Baylis Pain Management Equipment. Any modifications may not be attempted on equipment other than the Valleylab® RFG Series Generator, Neurotherm® Generator, STRYKER® RF Generator.

Potential complications associated with the use of this device include but are not limited to: infection, bleeding, nerve damage, visceral injury, increased pain, fever, and pyrexia. Special Handling Instructions

The HAL YARD* RF Nitinol Probe is delicate due to its small diameter RF electrode. Do not bend, kink, or stress the RF electrode. Do not crush or splice the probe cable. Doing so could damage the temperature sensing mechanism in the device.

Adverse Events

In Vivo RFI Exposure

Laboratory staff and patients can undergo significant x-ray exposure. Equipment. Any modifications may not be attempted on equipment other than the Valleylab® RFG Series Generator, Neurotherm® Generator, STRYKER® RF Generator. The HAL YARD* RF Nitinol Probes should be used to keep physical contact with the body. Apparent low power output or failure of the equipment to function properly must be used with the correct connector cable. Attempts to use it with another RF Generator Connector Cable will be used in conjunction with a radiofrequency generator to create lesions in nervous tissue.

Adverse Events

Check the compatibility and safety of combinations of other physiological monitoring and electrical apparatus to be used on the patient in addition to the RF lesion generator.

Contraindications

• Cardiac pacemaker patients
• Patients with an insertion of a cardioverter-defibrillator (ICD) or any other implanted electrical cardiac device.
• Patients with a pacemaker, pacemaker-dependent pacemaker, or any other implanted electrical cardiac device.
• Patients with a neurostimulator or other implanted electrical device.
• Patients with a pacemaker, pacemaker-dependent pacemaker, or any other implanted electrical cardiac device.
• Patients with a neurostimulator or other implanted electrical device.
• Patients with a pacemaker, pacemaker-dependent pacemaker, or any other implanted electrical cardiac device

Adverse Events

Lab assistants and patients can undergo significant x-ray exposure. Equipment. Any modifications may not be attempted on equipment other than the Valleylab® RFG Series Generator, Neurotherm® Generator, STRYKER® RF Generator. The HAL YARD* RF Nitinol Probes should be used to keep physical contact with the body. Apparent low power output or failure of the equipment to function properly must be used with the correct connector cable. Attempts to use it with another RF Generator Connector Cable will be used in conjunction with a radiofrequency generator to create lesions in nervous tissue.
Instructions for Use

CONNECTION CABLE
& RADIOFREQUENCY GENERATOR
NITINOL PROBE
RADIOFREQUENCY
HALEYARD

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