Instruction for Use PressureWire® Aeris, 20828 Rev 0F;
will be released as Rev 01
(Generated from approved Master Labeling Specification PW Aeris Rev 07F)

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- 0.014” (0.36 mm) guidewire
- Disconnectable transmitter – to be used with the guidewire it is delivered with
- Torque device

DESCRIPTION *(See Diagram 1)*

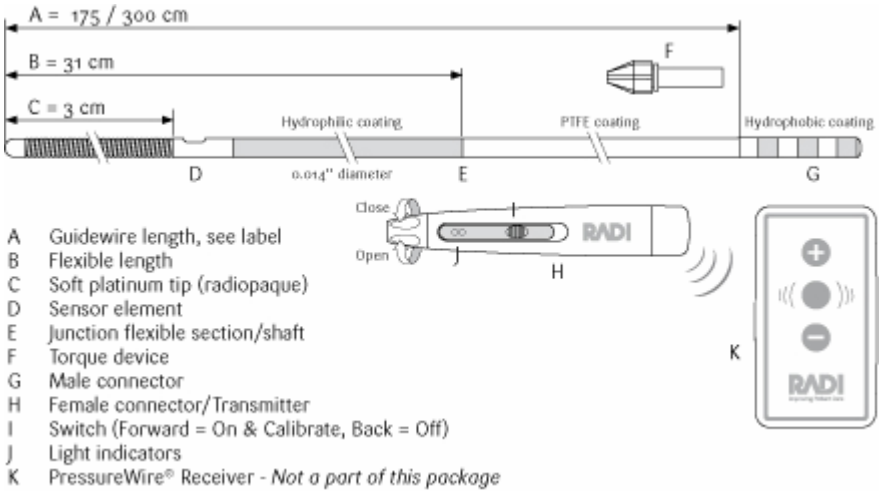
- PressureWire® 0.014” (0.36 mm) is a guidewire with a high fidelity sensor located just proximal to the 3 cm radiopaque shapeable tip.

- PressureWire® has a nominal diameter of 0.014” (0.36 mm).

- Refer to product label for guidewire length.

- The signals from the sensor can be used for measurements of cardiac and intravascular blood pressure and estimations of Fractional Flow Reserve (FFR).

Diagram 1: PressureWire®



A Guidewire length, see label
B Flexible length
C Soft platinum tip (radiopaque)
D Sensor element
E Junction flexible section/shaft
F Torque device
G Male connector
H Female connector/Transmitter
I Switch (Forward = On & Calibrate, Back = Off)
J Light indicators
K PressureWire® Receiver - *Not a part of this package*

1. INDICATION FOR USE

PressureWire® is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the heart and in the coronary and peripheral blood vessels.

2. CONTRAINDICATIONS

PressureWire® is contraindicated for use in the cerebral vasculature.

3. GENERAL WARNINGS

- PressureWire® is intended for single use only.
- Do not resterilize or reuse: the contents may be damaged or distorted.
- Prior to use and when possible during the procedure, inspect PressureWire® carefully for bends, kinks or other damage. Do not readjust any bend or kink.
- PressureWire® must not be used if it has been damaged in any way; otherwise, vessel/ventricle damage and/or inaccurate pressure signals or inaccurate torque response may occur.
- When introducing PressureWire® in a diagnostic case, flush the catheter and administer anticoagulation as for a standard catheterization procedure or clotting may occur.
- Do not torque PressureWire® without observing corresponding movement of the tip; otherwise vessel/ventricle trauma may occur.

- Always advance or withdraw PressureWire® slowly. Never push, withdraw or torque PressureWire® if it meets resistance.

4. GENERAL PRECAUTIONS

- Federal (USA) law restricts this device to sale by or on the order of a physician.

- PressureWire® is only intended to be used with PressureWire® Receiver.

- PressureWire® shall not be used with any other transmitter than the one which it is delivered with, or unreliable readings will be registered.

- Refer to instructions supplied with any interventional devices to be used in conjunction with PressureWire® for their intended uses, contraindications and potential complications.

- Do not use PressureWire® with atherectomy catheters. These systems may cause PressureWire® to fold back upon itself and become lodged in the atherectomy catheter. If this occurs, withdraw both the atherectomy catheter and PressureWire® simultaneously.

- PressureWire® does not give sufficient support for guiding catheter exchange.

- Do not use with interventional devices with a too short guidewire rail length as PressureWire® may fold or fracture during manipulation.

- Confirm the compatibility of PressureWire® diameter with the interventional device before actual use.

- Free movement of the guidewire within the interventional device is an important feature of a steerable guidewire system because it gives the user valuable tactile information. Test the system for any resistance prior to use.

- Adjust or replace the hemostatic valve with an adjustable valve if it is found to inhibit guidewire movement.

- When PressureWire® is disconnected from the transmitter during the procedure make sure the male connector does not come into contact with conductive surfaces thus avoiding unintentional connection with other equipment.

- False pressure readings may occur if the male connector is:
    - not dry, clean and free of coagulated blood.
    - not fully inserted into the bottom of the transmitter (indicated by yellow light).
    - bent or damaged.

- The PressureWire® Transmitter housing is protected against the effects of a discharge of a cardiac defibrillator. PressureWire® readings may however be affected by defibrillation. Attempt recalibration of PressureWire® after defibrillation according to “Recalibration” in the section Preparation for use.

- Avoid abrasion of PressureWire® coating. To avoid guidewire damage and possible shearing of the polymer coating, do not withdraw or manipulate PressureWire® in a metal cannula or sharp-edged object.

- If PressureWire® is taken out during the procedure in order to be reintroduced into the patient make sure the PressureWire® distal part is kept wet in the meantime. Make sure that the transmitter is kept dry.

- For optimal pressure measurement adjust the position of PressureWire® so that the sensor does not touch the atrial or ventricular walls, to avoid measurement artefacts due to movement.

- After use, the product may be a potential biohazard. Handle and dispose of PressureWire® in accordance with medical practice and applicable local, state and federal laws and regulations.

NOTE:
The transmitter contains silver oxide button type batteries with in total < 2% mercury, allowed to be put on the market according to the battery directive 2006/66/EG.The signal performance requires the batteries to be permanently affixed and the transmitter to be sealed, which, according to article 11 in the same directive, exclude the batteries from the requirement to be possible to remove. Dispose as ordinary potentially biohazardous material.

5. ADVERSE EVENTS

Potential complications which may be encountered during all catheterization procedures include but are not limited to: vessel dissection or occlusion, perforation, embolus, spasm, local and/or systemic infection, pneumothorax, congestive heart failure, myocardial infarction, hypotension, chest pain, renal insufficiency, serious arrhythmias or death.

6. PREPARATIONS FOR USE

Open the PressureWire® package using sterile technique and place PressureWire®, still attached to the packaging tray, on the sterile field.

- Make sure that PressureWire® is fully inserted into the transmitter.

- Fill the packaging coil with 10 ml (10 cc) of saline solution through the flush port located at the very inside of the coil on the packaging tray.

- Take care that the sensor element of PressureWire® is just submerged but not under a column of liquid (the tray should be lying flat).

- Activate the receiver by pressing the CONNECT button. The receiver is now ready to connect to PressureWire® (during 60 s), indicated by a flashing green light.

- Turn the transmitter on by pushing the slide button forward. A green light is activated. PressureWire® will now calibrate and search for a connection with the receiver.

- After successful calibration and connection to the receiver, the receiver indicators shift to steady green light and a double beep is heard.

    - If calibration fails the transmitter light turns yellow.

    - If a connection is not established and the green light on the receiver is still flashing, restart the transmitter by turning it off and then on again.

    - If a connection is not established within 60s the receiver returns to standby mode, indicated by a yellow light and a long beep. Reactivate the receiver by pressing the CONNECT button, then restart the transmitter by turning it off and then on again.

- After calibration, confirm that the pressure reading on the cathlab monitor is zero; re-zero the cathlab pressure channel if necessary. PressureWire® is now ready for use.

- Avoid turning off the transmitter during the case since PressureWire® will require a recalibration outside of the body.

    - RECALIBRATION
      If recalibration is necessary during the case, remove PressureWire® from the body and turn the transmitter off and then on again.

- Gently detach the transmitter from the packaging tray and carefully pull out the wire from the coil.

- Refer to Instructions for use for PressureWire® Receiver for complete instructions on handling of the receiver.

WARNING:
PressureWire® is a delicate instrument and should be handled carefully. Bending or excessive force during removal from packaging tray may damage the guidewire.

7. DIRECTIONS FOR USE, CORONARY MEASUREMENTS

7.1. Engage the guiding catheter using standard practice. Flush the catheter.

CAUTION:
A guiding catheter with 6F (2 mm) size or larger should be used to prevent damping of the arterial pressure signal. Larger size should be considered when large interventional catheters are used.

7.2. Carefully insert the distal tip of the guidewire into the hemostatic valve of the Y connector and then advance the wire into the catheter.

7.3. Position the sensor element of PressureWire® just outside of the tip of the guiding catheter.

7.4. Pull back the insertion tool out of the hemostatic valve.

7.5. Tighten the hemostatic valve.

7.6. Place the aortic pressure transducer at the same height as the patient´s heart. Make sure there is no remaining contrast fluid in the catheter, flush if necessary.

7.7. Verify that the aortic pressure from the guiding catheter and the PressureWire® pressure are similar.

7.8. To remove any residual pressure difference between aortic and PressureWire® pressure use the equalization function on the Cathlab monitor system or use the plus (+) and minus (–) buttons on PressureWire® Receiver. Refer to the Instructions for use for the Cathlab monitor or the Instructions for use for PressureWire® Receiver.

WARNING:
When introducing the guidewire, confirm that the catheter tip is free within the vessel lumen and not against the vessel wall. Failure to do so may result in vessel trauma upon guidewire exit of the catheter. Use the radiopaque marker of the catheter to confirm position.

7.9. Advance PressureWire® out of the guiding catheter. Use the torque device to steer PressureWire® to the desired position and perform pressure measurement.

WARNING:
Observe all PressureWire® movement. Whenever PressureWire® is moved or torqued, the tip movement should be examined under fluoroscopy.

CAUTION:
When difficult to reach a desired position, PressureWire® may be disconnected for

better handling. Carefully wipe and then dry the male connector before it is reconnected.

WARNING:
Torquing PressureWire® against resistance or repeated attempts to cross a total vessel occlusion may cause damage and/or fracture, which may lead to a portion of PressureWire® separating from the tip.

NOTE: To calculate Fractional Flow Reserve (FFR) apply maximum hyperemic stimulus according to clinical standard practice.

CAUTION:
Failure to achieve maximum coronary and myocardial hyperemia may result in invalid FFR.

CAUTION:
Do not measure pressure when the sensor element of PressureWire® is in sharp curves, since this might result in pressure artefacts.

WARNING:
Excessive manipulation when sensor element (D) or tip of PressureWire® is located in sharp bend may cause damage or tip fracture. If the guiding catheter is in an anatomically severe or sharp bend, for example a tortuous subclavian artery or adjacent vessel position, the junction between the shaft and the flexible distal section of the wire (E), 31 cm from the tip, may be vulnerable to kinking or fracture. Avoid use of PressureWire® via a radial or brachial approach unless this approach is based on medical necessity.

If a decision is taken to continue with an interventional procedure, follow these instructions:

8. DIRECTIONS FOR USE, INTERVENTIONAL PROCEDURE

CAUTION:
A guiding catheter with 6F (2 mm) size or larger should be used to prevent damping of the arterial pressure signal. Larger size should be considered when large interventional catheters are used.

8.1 Inspect and prepare the interventional device according to the manufacturer's instructions.

8.2 Disconnect the transmitter from PressureWire®, then remove the torque device by loosening the screw and gently withdraw it.

8.3 Carefully advance the interventional device over PressureWire® male connector and proceed according to standard clinical practice.

8.4 Carefully wipe and then dry the male connector before it is reconnected.

8.5 Reconnect PressureWire® to the transmitter, taking care to gently and fully insert the male connector and to tighten the cap on the transmitter.

8.6 Treat the lesion using standard practice.

8.7 To evaluate the result of the intervention, withdraw the interventional device and perform pressure measurement.

CAUTION:
An interventional device may cause an underestimation of coronary pressure if left in artery or guiding catheter during pressure measurement.

NOTE: To calculate Fractional Flow Reserve (FFR) apply maximum hyperemic stimulus according to clinical standard practice.

CAUTION:
Failure to achieve maximum coronary and myocardial hyperemia may result in invalid FFR.

8.8 When the procedure is finished, verify pressures by:

- Position the sensor element of PressureWire® just outside of the tip of the guiding catheter.
- Flush any remaining contrast fluids.
- Pull back the insertion tool out of the hemostatic valve.
- Tighten the hemostatic valve.
- Verify that the pressures registered by the guiding catheter and PressureWire® are the same.

9. DIRECTIONS FOR USE, INTRACARDIAC MEASUREMENTS

WARNING:
When introducing the guidewire, confirm that the catheter tip is free within the heart lumen and not against the heart wall. Failure to do so may result in ventricle trauma upon guidewire exit of the catheter.

WARNING:
Torquing PressureWire® against resistance may cause damage and/or fracture of PressureWire®, which may lead to a portion of PressureWire® separating from the tip.

WARNING:
Positioning of catheters and guide wires in the ventricles is potential arrhythmogenic. It should never be done without ECG monitoring and the presence of a functioning defibrillator.

WARNING:
Avoid using PressureWire® in the ventricles if the patient has a prosthetic mechanical valve. PressureWire® may become trapped and disrupt the function of the valve, leading to serious injury or death.

CAUTION:
A standard 0.035" J-shaped guidewire is recommended to advance the catheter and to give support when crossing heart valves. Never use PressureWire® for this purpose.

9.1 Use a standard 0.035" J-shaped guidewire to position a multipurpose catheter in the heart at the position of interest, follow standard clinical practice depending on application.

9.2 With the catheter securely in place, replace the standard guidewire with PressureWire®.

9.3 Insert the distal tip of PressureWire® into the hemostatic valve and then advance the wire into catheter.

9.4 Advance PressureWire® into the position of interest.

WARNING:
Observe all PressureWire® movement. Whenever PressureWire® is moved or torqued, the tip movement should be examined under fluoroscopy.

9.5 Pull back the catheter to a stable position outside the heart valve, leaving only PressureWire® at the measurement position.

CAUTION:
Whenever absolute blood pressure measurements are obtained, the pressure registered by the catheter and PressureWire® should be properly matched. For this purpose the catheter should have a residual lumen large enough to prevent damping of the corresponding intracardiac pressure.

PRESSURE PERFORMANCE SPECIFICATION

Operating pressure:	-30 to +300 mmHg
Zero Thermal Effect:	0.3 mmHg/°C
Sensitivity Thermal Effect:	0.3%/°C
Zero drift:	< 7mmHg/h

Total Accuracy for the combination of PressureWire® and PressureWire® Receiver:
±1mmHg plus ±1% of reading (over the pressure range – 30mmHg to 50mmHg)
±3% of reading (over the range 50mmHg to 300mmHg)

Delay time: <10 ms

Typical performance data for pressure is valid in the temperature range of 35°C to 42°C during a measuring time of less than 1 hour.

RADIO SIGNAL SPECIFICATION

Frequency Range:	2.4000-2.4835GHz (ISM-band)
Type:	Frequency Hopping Spread Spectrum
Radiated power:	1mW peak, 70µW average (EIRP)
Range:	0 - 2m

Note: Radio range is reduced by objects and walls, keep transmitter and receiver in line of sight wherever possible.

FCC STATEMENT

FCC ID: U4L01080410 FCC identifier for the transmitter

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

WARNING - Changes or modifications not expressly approved by Radi Medical Systems AB could void the user´s authority to operate the equipment.

ENVIRONMENTAL CONDITION
Ambient temperature: 15-35°C
Ambient temperature fluctuation : ± 5°C
Relative air humidity: 30- 75%
Ambient pressure: 425-850 mmHg

TRANSPORT
Transportation temperature: -25- 70°C
Relative air humidity: 10- 95%

STORAGE
Store at room temperature in a dry, dark place.

TRANSMITTER LIGHT INDICATORS

Light indicators	Explanation
Green steady light	Transmitter on
Green pulsating light proportional to blood pressure	Normal operation
Yellow steady light	PressureWire® disconnected from transmitter. Re-insert PressureWire® firmly into transmitter.
Green pulsating light & Yellow slow blinking light	Battery level low It is recommended to finish case or to exchange PressureWire®.
Yellow fast blinking light	Error. Possible cause: o Battery level too low for operation o Internal error Attempt restart by removing PressureWire from body and turn the transmitter off and on again.

COMPLIANCE WITH REGULATORY REQUIREMENTS

Hereby, Radi Medical Systems AB, declares that this PressureWire® is in compliance with the essential requirements and other relevant provisions of Medical Device Directive (93/42/EEC), Radio and Telecommunications Terminal Directive (199/5/EC) and QSR

Guidance and manufacturer's declaration - electromagnetic emissions
PressureWire® system is intended for use in the electromagnetic environment specified below. The customer or the user of PressureWire® system should assure that it is in such an environment.

Emission test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The PressureWire® system uses RF energy only for its internal function. Therefore, its RFemissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The PressureWire® system is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies building for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations /flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity
The PressureWire® system is intended for use in the electromagnetic environment specified below. The customer or the user of the PressureWire® system should assure that it is in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	N/A 1) 2)	N/A
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	N/A 2)	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles 5% U_T (>95% dip in U_T) for 5 sec	N/A 1)	N/A
Power frequency (50/60 Hz) magnetic filed IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level. 1) No mains power input 2) Patient connection			

Guidance and manufacturer's declaration - electromagnetic immunity

The PressureWire® system is intended for use in the electromagnetic environment specified below. The customer or the user of the PressureWire® system should assure that it is in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the PressureWir® system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF	3 Vrms	N/A	$d = 1,2\sqrt{P}$

IEC 61000-4-6	150 kHz to 80 MHz	1)	
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	d = 1,2√ P 80 MHz to 800 MHz d = 2,3√P 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey the PressureWire® system is used exceeds the applicable RF compliance level above, the PressureWire® system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PressureWire® system.

b) Over the frequency range 150KHz to 80MHz, field strengths should be less than 3 V/m.

1) No mains power input

Recommended separation distances between portable and mobile RF communications equipment and the PressureWire® system

The PressureWire® system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PressureWire® system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PressureWire® system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1,2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1,2\sqrt{P}$	**800 Mhz to 2,5 GHz** $d = 2,3\sqrt{P}$
0,01	0,12	0,12	0,24
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance (*d*) in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

RoHS DECLARATION (for the Chinese IFU only)

No toxic and hazardous substances according to RoHS contained.

PATENTS

USA:	Re 35648, Re 39863, 4996082, 5085223, 5938624, 6089103, 6112598, 6142958, 6167763, 6196980, 6248083, 6336906, 6409677, 6428336, 6565514, 6615667, 6672172, 6754608, 6908442
Europe:	877574, 907335, 968547, 973438, 1012912, 1076511, 1125548, 1310215, 1475036, 1165171
Canada:	1271930
Sweden:	460396, 506135, 523337
Japan:	2659944, 2719425, 3675835, 3679419, 3692014, 3692035, 3774237, 3830528, 3880884
	Other patents pending worldwide

WARRANTY AND LIMITATIONS

Although PressureWire®, hereafter referred to as “product”, has been manufactured under carefully controlled conditions, Radi Medical Systems AB, hereafter called Radi, has no control over the conditions under which the product is used. Radi, therefore disclaims all warranties, both expressed and implied, with respect to the product, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Radi shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind Radi to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

PressureWire® is developed and manufactured according to Medical Device Directive, Radio and Telecommunication Terminal Equipment Directive 199/5/EC and QSR (US).

PressureWire® and RadiAnalyzer® are registered trademarks of Radi Medical Systems AB.

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SYMBOLS WITH EXPLANATIONS:

 Caution, (Attention consult accompanying documents)

 Consult operating instructions

 Expiry date (2 years from manufacturing date)

CONTENTS Contents of the package

REF Catalogue number

LOT Lot number.

QTY Quantity

 Type CF equipment

 Equipment includes RF transmitter

 Electrostatic sensitive device

 Do not use if package is damaged.

 For single use only. Do not reuse.

Do not re-sterilize

Sterilized using Ethylene Oxide

The transmitter contains silver oxide button type batteries with in total < 2% mercury, allowed to be put on the market according to the battery directive 2006/66/EG. The signal performance requires the batteries to be permanently affixed and the transmitter to be sealed, which, according to article 11 in the same directive, exclude the batteries from the requirement to be possible to remove. Dispose as ordinary potentially biohazardous material.

CE 0124 **0413** Complies with the Medical Device Directive 93/42/EEC and Radio and Telecommunication Terminal Equipment Directive 199/5/EC.

FCC ID: U4L01080410 FCC identifier for the transmitter

No toxic and hazardous substances according to RoHS contained. (This mark for the Chinese market only!)

Rx Only
Caution: Federal law (USA) restricts this device to sale by or on the order of a Physician