remedē[®] System

Inventory Reference Guide

| | ITEM | MANUFACTURER | PART/ORDER NUMBER | DESCRIPTION | MINIMUM INVENTORY QUANTITIES | | |
|-----------------------|-----------|----------------------|----------------------|---|------------------------------|--------|--------|
| | | | | | 1 CASE | 2 CASE | 3 CASE |
| Manufacturer Specific | PG | ZOLL Respicardia | 1001, 1100, 1600 | rem edē PG | 2 | 3 | 4 |
| | Lead | ZOLL Respicardia | 4065, 4165, 4665 | respi stim LQS, 65cm | 2 | 3 | 4 |
| | Lead | ZOLL Respicardia | 3102, 3652 | respi stim R Lead – 24mm dia., normal length | 1 | 2 | 3 |
| | Lead | ZOLL Respicardia | 3103, 3653 | respi stim R Lead – 20mm dia., extended length | 1 | 2 | 3 |
| | Catheter | ZOLL Respicardia | 7120-S | respi guide 120° | 2 | 3 | 4 |
| | Catheter | Merit Medical | 57538CS-WOR | Impress 5F CS Catheter, 75cm | 2 | 3 | 4 |
| | Catheter | Merit Medical | 57538CSV-WOR | Impress 5F CS VERT Catheter, 75cm | 2 | 3 | 4 |
| | Accessory | Pressure Products | SS-SA-09 | 9F Sealing Adapter | 2 | 3 | 4 |
| | Accessory | ZOLL Respicardia | 1007 | Test Adapter (Reps Carry) | 2 | 3 | 4 |
| | Accessory | Medtronic | 6232ADJ | Adjustable Slitter | 2 | 3 | 4 |
| Physician Preference | Guidewire | Physician preference | | 0.014" Floppy | 3 | 6 | 9 |
| | Guidewire | Physician preference | | 0.014" Stiff | 2 | 3 | 4 |
| | Guidewire | Physician preference | | 0.018" | 2 | 3 | 4 |
| | Guidewire | Physician preference | | 0.035" angled floppy | 2 | 3 | 4 |
| | Guidewire | Physician preference | | 0.035" access J-wire | 2 | 3 | 4 |
| | Accessory | Physician preference | | Y-connector and hemostasis valve | 2 | 3 | 4 |
| | Accessory | Physician preference | | IS-1 standard Port plug (For models 1001, 1100) | 3 | 5 | 7 |
| | Accessory | Physician preference | | 8Fr x 13cm hemostatic introducer sheath, splitable | 2 | 3 | 4 |
| | Accessory | Physician preference | | Disposable pacing cables | 2 | 3 | 4 |
| | Accessory | Physician preference | | Programming Wand Sterile Sleeve | 2 | 3 | 4 |
| | Accessory | Physician preference | | Guidewire Torque Device | 2 | 3 | 4 |

Important Safety Information

The remedē® System is indicated for moderate to severe Central Sleep Apnea (CSA) in adult patients. A doctor will need to evaluate the patient's condition to determine if the remedē System is appropriate. The remedē® System should not be implanted during an active infection and patients will not be able to have diathermy (special heat therapies). The device is MR Conditional. The conditions and precautions can be found in the remedē System MRI guidelines manual. The remedē System may be used with another stimulation device such as a heart pacemaker or defibrillator; special testing will be needed to ensure the devices are not interacting. As with any surgically implanted device, there are risks related to the surgical procedure itself which may include, but are not limited to, pain, swelling, and infection. Once the therapy is turned on, some patients may experience discomfort from stimulation and/or from the presence of the device. The majority of these events are resolved either on their own or by adjusting the therapy settings. The **rem**edē System may not work for everyone. There are additional risks associated with removing the system. If it is decided to remove the system, another surgery will be required. Be sure to understand all the risks and benefits associated with the implantation of the **rem**edē System. For further information please visit remede.zoll.com, call 952-540-4470 or email info@remede.zoll.com. **Contraindications:** The **rem**edē System is contraindicated for use in patients with an active infection. See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.

Rx Only. The remedē® System, remedē® EL System, and remedē® EL-X System have received FDA approval.

The remedē® System model 1001 has received CE Mark approval.

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