

## Power Unit (87-9132)

The Power Unit is a single-use, provided sterile, battery pack for the CORE Shoulder medical device system (87-9130).



This IFU is available online; either scan the QR Code or go to: <https://coreifu.com/shld>

Only available in English.



**Packaging:** Double barrier sterile pouch. Product identification is provided on the external label of each pouch and the outer carton.


**Sterilization:** The device is supplied sterile (Ethylene Oxide “EtO”) in a sealed double barrier pouch which bears the sterilization and expiry dates. After the expiry date passes, the Power Unit cannot be used anymore. Ensure the sterile packaging is intact and handled with care. The device cannot be sterilized in a steam sterilizer (autoclave). The manufacturer and distributor accept no liability for any attempt of reprocessing.

**Storage:** Handle with care. Store in a dry place at room temperature (no extremes). Avoid direct sunlight. Keep storage area clear to avoid damage to the sterile packaging. Improper handling or care as well as misuse can damage the sterile barrier or device.

**Suggestion:** Keep the Power Unit in its own packaging until use of the CORE Shoulder system.

**Traceability:** To ensure medical device traceability, the user should attach the peel-off Patient Sticker Labels (supplied in the carton) to the patient’s clinical documentation.

**Post-Use Disposal:** The Power Unit contains a lithium battery which shall be discarded after the operation. To assist with opening the Power Unit, insert any metal tool into the slot on the underside and pry open. Dispose of the battery per local regulations. Dispose of the electronics and plastic housings per local regulations.

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| <p><b>WARNINGS:</b></p>  | <ul style="list-style-type: none"> <li>• <b>Do <u>not</u> use if sterility expiration date is not legible. It is not allowed under any circumstances.</b></li> <li>• <b>If the Power Unit is dropped on the floor, it must be discarded.</b></li> <li>• <b>When handling the opened Power Unit and exposed battery, do <u>not</u> touch the patient.</b></li> <li>• <b>If battery breaks/leaks electrolyte, wear personal protective equipment (gloves/goggles/mask) and clean the spill with cloth and water. Do <u>not</u> use alcohol. Seal battery in a sturdy container and dispose per local regulations. If electrolyte spilled onto Power Unit, clean it with cloth and water.</b></li> <li>• <b>Do <u>not</u> allow the lithium battery to be placed into biohazard waste. Biohazard waste could be incinerated, which could cause intense fire and/or explosion of the lithium battery.</b></li> </ul> |
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