



ADAP-2RL SAFETY ADAPTOR



Basic UDI-DI: 081307902ADAP3K

INTENDED PURPOSE:

The ADAP Family of Reusable Adapters are considered accessories to an active implantable device and are intended for transient use. The ADAP Family are intended to be used by professional medical personnel and act as an interface between a compatible pacing system analyzer or external pacing generator and compatible Remington Medical cable models or compatible lead test cables (ADAP-2RL). The ADAP Family act as conductors carrying the signal to/from the patient via an extension cable and to/from the instrument. The ADAP Family is a reusable device.

The ADAP-2RL is designed to interface between a compatible pacing system analyzer or external pacing generator and a compatible Lead Test Cable.

INDICATIONS FOR USE:

ADAP-2RL is intended to be used by professional medical personnel for the interfacing between compatible pacing system analyzers (PSA) or external pacing generators (EPG) and a compatible Lead Test Cable. The ADAP-2RL is intended for all patient populations. ADAP-2RL does not have any therapeutic or diagnostic indications or claims.

WARNINGS/PRECAUTIONS:

1. The ADAP-2RL Safety Adaptor is supplied non-sterile but must be cleaned per the instructions prior to use.
2. Do NOT autoclave.
3. Physicians are required to inspect the integrity of the ADAP-2R prior to use.
4. No modification of the ADAP-2R is allowed.

CONTRAINDICATIONS:

The ADAP Family of Reusable Adapters is intended for all patient populations; however, physician judgment is required regarding certain patient populations for pacing procedures (i.e., use in patients with conditions that may affect temporary or permanent pacing).

INSTRUCTIONS FOR USE:

1. Open the envelope, remove the ADAP-2RL, and complete the cleaning process.
 - a. The ADAP-2RL should be cleaned thoroughly with a mild detergent or 70% isopropyl alcohol and then allowed to air dry completely before subsequent use.
2. Connect the ADAP-2RL to the compatible EPG or PSA as follows:
 - a. Insert the redel connector into the port on the compatible pacing system analyzer or external pacing generator. Gently pulling on the redel connector will verify a secure connection.
 - b. To remove the safety adaptor from the compatible EPG or PSA, refer to the technical manual supplied with the EPG or PSA for insertion and releasing mechanisms specific to the particular EPG or PSA.
3. Connect a compatible Lead Test Cable to the ADAP-2RL as follows:
 - a. Align the cable connector with the Lemo receptacle end of the ADAP-2RL. Fully insert the connector until it “clicks” into the receptacle.
 - b. To disconnect the cable from the safety adaptor, grasp the cable’s connector while pressing in the release tab and remove from the adaptor. Pulling on the wire may result in damage to the cable or adapter.

DISPOSAL:

- 1. Dispose of the damaged or unusable ADAP-2RL in an environmentally friendly way as contaminated medical waste.

Any serious incident which has occurred in relation to the ADAP-2RL should be reported to Remington Medical, Inc. and the competent authority of the Member State in which the user and/or patient is established. The Summary of Safety and Clinical Performance (SSCP) for Remington Medical Adapters is available in the European database on medical devices (Eudamed) where it is linked to the Basic UDI-DI. The URL to the Eudamed public website is: <https://ec.europa.eu/tools/eudamed>. The SSCP is also available online at remmed.com

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NON
STERILE

Non-sterile

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MD

Rx Only

RoHS
COMPLIANT
LEAD-FREE

RoHS Compliant
Lead-Free

DO

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