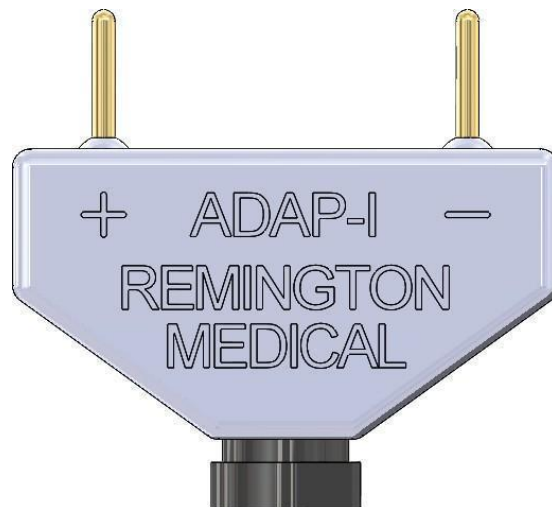


ADAP-I SAFETY ADAPTOR



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-I is designed to interface between the 97 connector used on compatible Remington Medical cable models, and compatible old models of external pacing generators (EPG) [old model is the acceptance of exposed 2mm pins]. Also, ADAP-I is designed to be used with compatible pacing system analyzers (PSA) that have sockets that accept 2mm pins with 31.25mm separation between the pins.

INDICATIONS FOR USE:

ADAP-I is intended to be used by professional medical personnel for the interfacing between the 97 connector used on compatible Remington Medical cable models and compatible old models of external pacing generators (EPG) [old model is the acceptance of exposed 2mm pins]. Additionally, ADAP-I is designed to be used with compatible pacing system analyzers (PSA) that have sockets that accept 2mm pins with 31.25mm separation between the pins. The ADAP-I is intended for all patient populations. ADAP-I does not have any therapeutic or diagnostic indications or claims.

WARNINGS/PRECAUTIONS:

1. When making pacing connections using the ADAP-I, polarity must be verified.
2. The ADAP-I Safety Adaptor is supplied non-sterile but must be cleaned per the instructions prior to use.
3. Do NOT autoclave.
4. Physicians are required to inspect the integrity of the ADAP-I prior to use.
5. No modification of the ADAP-I 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-I, and complete the cleaning process.
 - a. The ADAP-I 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-I to the compatible EPG or PSA as follows:
 - a. Verifying polarity, completely insert the exposed ADAP-I pins into the connector sockets on the compatible EPG or PSA. Gently pulling on the ADAP-I 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 the compatible Remington Medical cable models to the ADAP-I as follows:
 - a. Align the 97 cable connector with the female 97 receptacle of the ADAP-I. Fully insert the 97 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 removing the adaptor. Pulling on the wire may result in damage to the cable or adapter.

DISPOSAL:

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

Any serious incident which has occurred in relation to the ADAP-I 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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Rx Only

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