

# ADAP-2R 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 nalyzer 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-2R is designed to interface between a compatible pacing system analyzer or external pacing generator and compatible Remington Medical cable models.

## **INDICATIONS FOR USE:**

ADAP-2R is intended to be used by professional medical personnel for the interfacing between compatible pacing system analyzers (PSA) or external pacing generator (EPG) and compatible Remington Medical cable models. The ADAP-2R is intended for all patient populations. ADAP-2R does not have any therapeutic or diagnostic indications or claims.

## WARNINGS/PRECAUTIONS:

- 1. The ADAP-2R 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-2R, and complete the cleaning process.
  - a. The ADAP-2R 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-2R 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 the compatible Remington Medical cable models to the ADAP-2R as follows:
  - a. Align the 97 cable connector with the female 97 receptacle of the ADAP-2r. Fully insert the 97 connector until it "clicks" into the receptacle.
  - b. Observe atrial or ventricular connection.
  - c. For single chamber implants, insert cable into the connector marked "V".
  - d. For dual chamber implants, insert one cable into connector marked "V" and one cable into connector marked "A".
  - e. 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-2R in an environmentally friendly way as contaminated medical waste.

Any serious incident which has occurred in relation to the ADAP-2R 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: <u>https://ec.europa.eu/tools/eudamed</u>. The SSCP is also available online at <u>remmed.com</u>



IF-00009 Rev. B Date: MAY 2024