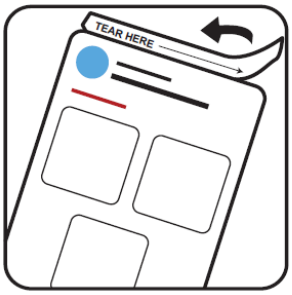
Instructions for Use
TZ Medical Defibrillator Pads

Indications for Use: TZ Medical disposable electrodes are intended for use by trained professionals in hospitals, doctor's offices and Emergency Medical Services for low-energy defibrillation, transcutaneous pacing, cardioversion and monitoring.

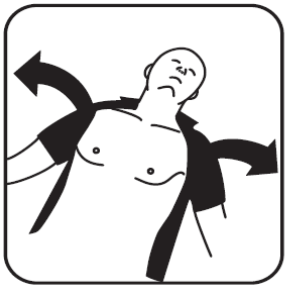
Designed for single use with multiple defibrillators, either monophasic or biphasic defibrillation, pacing, monitoring, or cardioversion either directly or through adaptors.

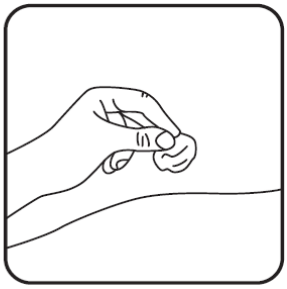
Directions for Use:

Tear open the pouch and remove the electrodes from pouch



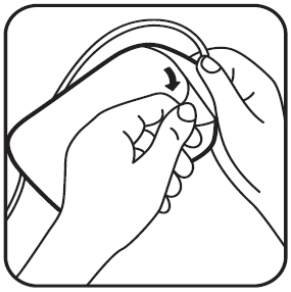
Remove the patient's clothing and ensure the application area is clean and dry, clipping excess hair.





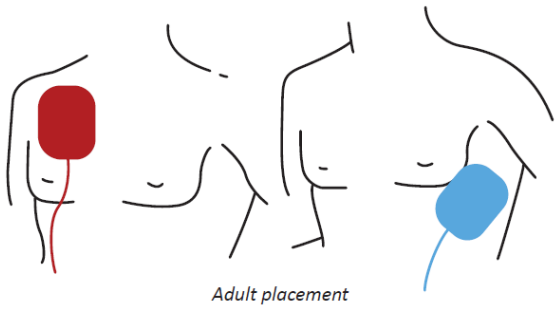
DO NOT use alcohol or tincture of benzoin, leave no residue.

Peel the release liner away from the electrode pads at the location indicated by the arrows *(Arrow indicates peel location).*



Apply the electrodes to the patient by rolling the electrode from top to bottom.

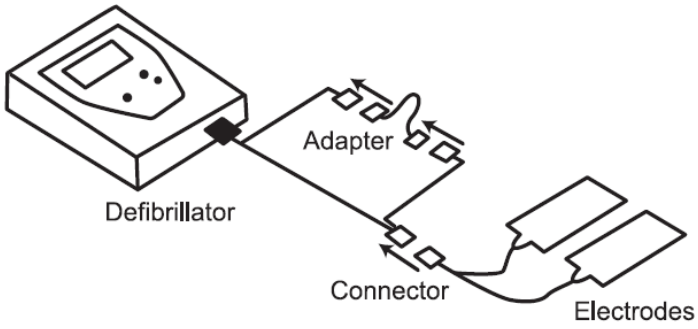
Ensure the total surface area of the electrode is in contact with the skin.



Adult placement

DO NOT reposition or trap air under pads.
Connect the electrodes to the defibrillator using appropriate connector or adapter cable.

DO NOT touch the patient during defibrillation



Notes:
1. Attach both EKG monitoring electrodes and defibrillation electrode pads for demand pacing.
2. After use, the product may be a potential biohazard.
3. Handle and dispose of electrodes in accordance with institution protocol and follow local, state and federal laws.
4. May need appropriate adapter cable.

REF	Catalog Number
Rx Caution: Rx Only	Caution: Federal Law (US) restricts device sale by or on the order of a physician
	Contents of this package
	Do not Reuse Single Use only
LOT	Lot number
	Use By date
	Manufacturer
	Do not use if package is damaged
	Consult Instructions For Use
0ºC 40ºC	For maximum performance, storage should not exceed 30 days: Maximum Temperature. 40ºC; Minimum Temperature, 0ºC
LATEX	No Latex was used in the manufacturing of this product
NON STERILE	Product is package non-sterile
STERILE R	Sterilized using irradiation
	Caution, consult directions for use

Contraindications:

For long term use, apply a new set of electrodes every 24 hours or when the pads are not adhering properly.

Warnings/Cautions:

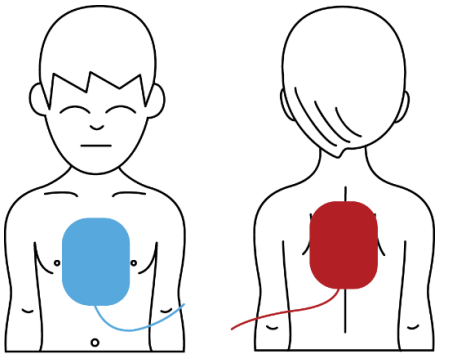
1. Federal law (USA) restricts this device to sale by or on the order of a physician. This product may be used by authorized medical personnel only.
2. Misuse of electrodes may cause patient burns.
3. Electrodes should be kept well clear of other electrodes or metal parts in contact with the patient.
4. For Universal Function Electrode use (i.e. Monitoring, Defibrillation, and Pacing), these electrodes must be used in conjunction with AED and ECG amplifiers that have been designed specifically to compensate for large DC offsets.
5. Adult electrodes can withstand 24 hours of monitoring or 50 defibrillations or 8 hours of pacing.
6. For extended periods of pacing (greater than 30 minutes) periodically examine the patient's skin for irritation.
7. The ability to effectively clean and reserialize this single use device has not been established and subsequently re-use may adversely affect the performance, safety and/or sterility of the device.
8. Misuse of electrodes may cause patient burn.
9. Foam adhesive is medical grade and biocompatible. Removal of adhesive may cause irritation to the skin.
10. Demand pacing requires separate ECG electrodes and leads for monitoring.
11. **DO NOT** fold, trim, crush, or store under heavy objects.
12. **DO NOT** use if electrodes or gel is dry, damaged or expired.
13. **DO NOT** discharge hand held paddles on these electrodes.
14. **DO NOT** open package until immediately prior to use.
15. **DO NOT** exceed 360J while defibrillating.
16. **DO NOT** apply to broken skin.
17. Pacing requires separate leads for monitoring.
18. Single use product, not intended to be applied or used

Pediatric Pads:

Intended Use:
Pediatric patients whose weight is less than 25Kg.

Additional Warnings:
1. Initial dose not to exceed 2J per Kilogram.

Pad Application:*
Pediatric Placement:



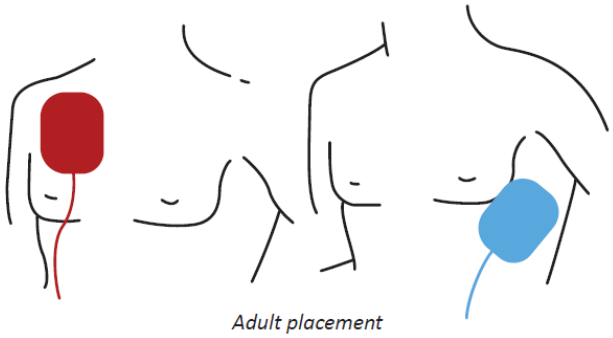
Pediatric placement

Anterior | Posterior

For Pediatric Use:
Manual Defibrillator:
≥10 kg (22lbs)
AED or AED Mode:
≥25 kg (55 lbs) ≥8 years old

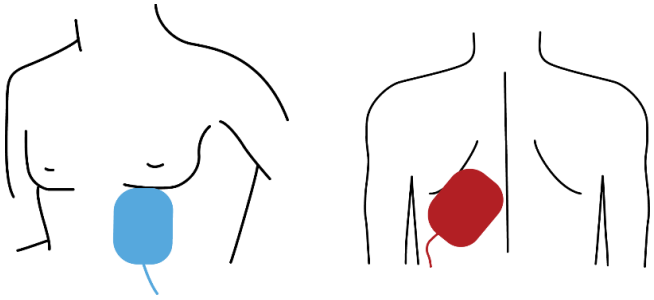
Adult Pad Application Options:

Standard Anterior-Adult Placement



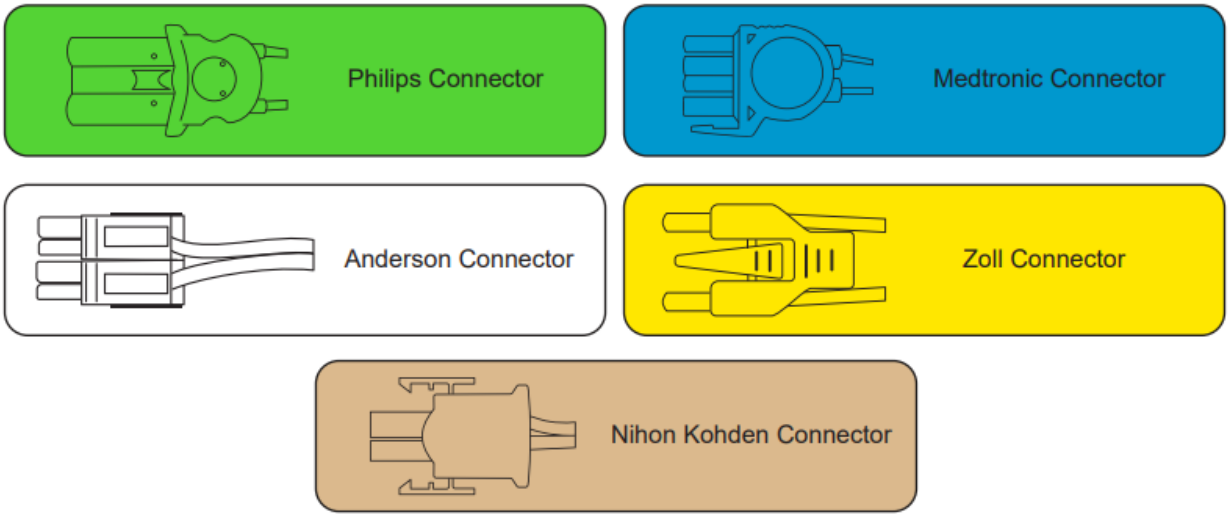
Adult placement

Optional Anterior-Posterior Placement
For Cardioversion



Anterior/Posterior placement

Defibrillator Connector Pin Options:



** Nihon Kohden® Connectors available in countries where NK defibrillators have obtained regulatory approval

Sterile Electrode Connector Instructions

T1 Anderson Connector Instructions

1. The enclosed multi-functional electrodes are designed to be used for rescue defibrillation.
2. Prior to adhering the electrodes to the patient, ensure the anterior and posterior placement sites are dry.
3. Using sterile technique, open and remove the electrodes from the package, transferring both electrodes onto the sterile field.
4. Pass RED back electrode off of sterile field, remove adhesive liner, and place on back of patient.
5. Using sterile technique, remove BLUE Apex/front electrode adhesive liner, and place electrode on patient's chest.
6. After electrodes are positioned, drop the BLUE Apex/front electrode lead wire connector off the sterile field.
7. Mate the BLUE electrode wire connector to the RED connector previously placed in the back position. Fig 1.

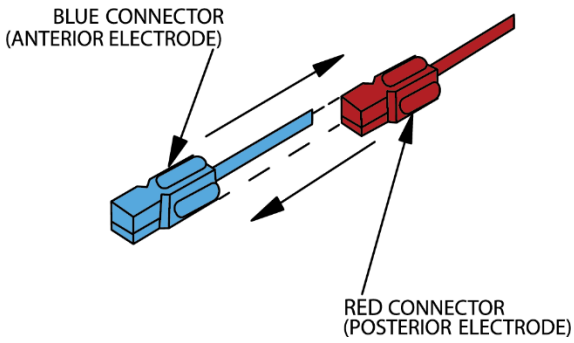


Fig. 1.

8. Slide recessed groove on the underside of the BLUE connector over raised notch on top surface of RED connector ensuring surface(s) of interface connections are flush. Fig. 2.

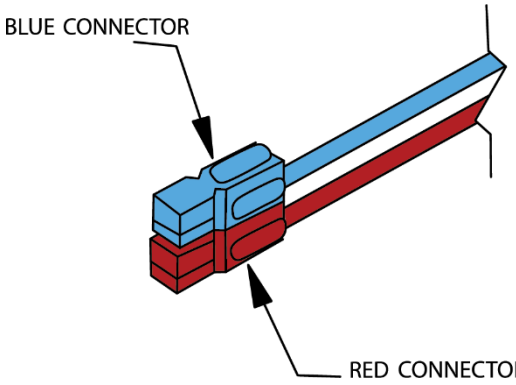


Fig. 2.

9. Mate electrode connections to Patient Delivery Cable connection as shown in Fig. 3 by rotating the cable to match the electrode color-coded connection. Listen for a click as interconnection is complete, Fig. 4.

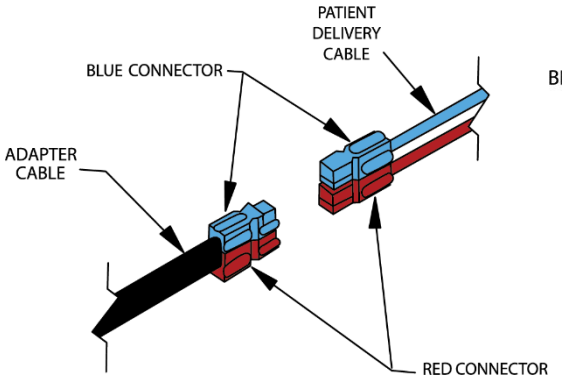


Fig. 3.

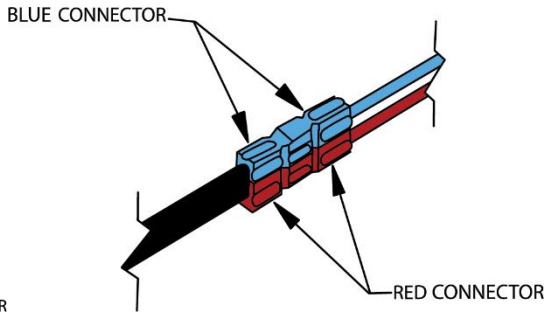


Fig. 4.

10. To remove electrodes, use the wire as a handle, peel slowly toward the opposite side, parallel to patient skin.

Z1 Zoll® Connector Instructions

1. The enclosed multi-functional electrodes are designed to be used for rescue defibrillation.
2. Prior to adhering the electrodes to the patient, ensure the anterior and posterior placement sites are dry.
3. Using sterile technique, open and remove the electrodes from the package, transferring both electrodes onto the sterile field.
4. Pass RED back electrode off of sterile field, remove adhesive liner, and place on back of patient.
5. Using sterile technique, remove BLUE Apex/front electrode adhesive liner, and place electrode on patient's chest.
6. Mate the RED electrode wire to the Zoll® connector opposite of BLUE electrode wire. Fig. 1

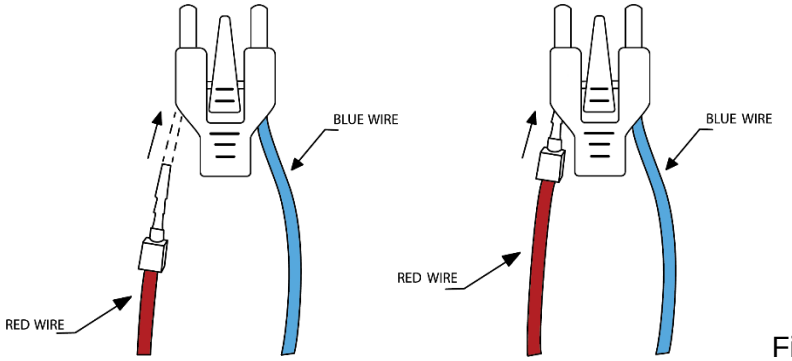


Fig.1

7. Slide RED electrode wire into Zoll® connector until click is heard. Fig. 2.

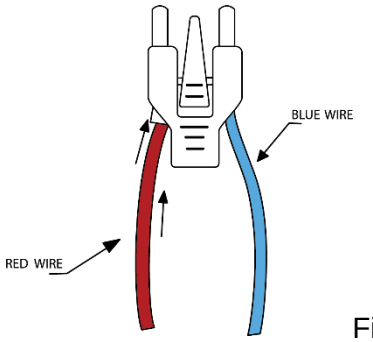


Fig. 2.

8. After RED wire is secure, slide clear spacer up into Zoll® connector until not visible. Fig. 3

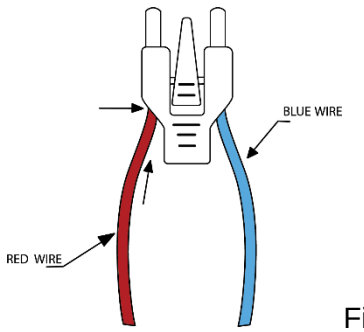


Fig. 3

Manufacturers' Information

LIMITED WARRANTY

TZ Medical Warrants the device electrode pads to be free from material and workmanship defects until the expiration date is reached. TZ Medical shall not assume liability for consequential, incidental, or special expense directly relating from the product usage. Warranty liability and the buyer's exclusive remedy is expressly limited to replacement of the pad, used under normal use and service, by the Company as having been defective in materials or workmanship. The buyer is directly obligated to return the device to the Company for examination and replacement.

No employee, representative or agent of TZ Medical has the authority to bind, amend or alter the warranty. Any purported alteration amendments, or implied representation shall not be enforceable by the buyer against TZ Medical.

THIS WARRANTY IS IN LIEU OF ANY IMPLIED OR EXPRESSED WARRANTIES, INCLUDING THOSE OF MERCHANTABILITY OR FITNESS FOR ANY OTHER OBLIGATION ON THE PART OF TZ MEDICAL.

TZ Medical, Inc.
17750 SW Upper Boones Ferry Rd,
Suite #150
Portland, OR 97224
Office: 800.944.0187
Fax: 503.639.0239

PATENT AND TRADEMARKS

This device may be covered by one or more U.S or international patents.

*Compliant and up-to-date with American Heart Association (AHA) guidelines (2000/2010) and American Red Cross (ARC) BLS for Healthcare Provider's Handbook (2011/2015)

CE 0459

A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

EC REP

EU Authorized Representative:
CEPartner4U
Esdoornlaan 13
3951 DB Maarn
The Netherlands
www.cepartner4u.eu