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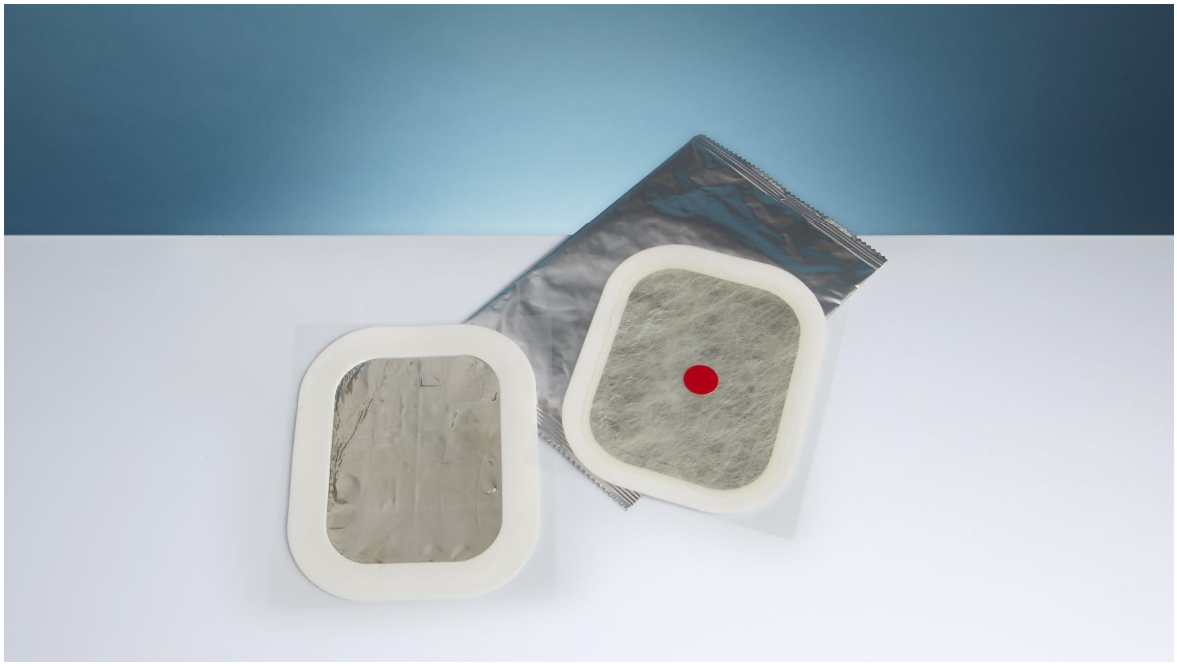
ET3010 Adhesive Pregelled Pads for Defibrillation. Adult Patient Use



Technical Specifications

Materials

Baking Material:	Waterproof flexible white PE foam, closed cell, with biocompatible acrylic adhesive
Conductive Area:	Aluminium / PET film with acrylic based hydrogel, biocompatible
Release Liner:	PET
Pouch:	PET / aluminium / PE film

Biocompatibility Tests

Dermal Sensitization (ISO 10993-10):	No sensitizing
Dermal Irritation (ISO 10993-10):	Negative intracutaneous irritation test
Cytotoxicity (ISO 10993-10):	Non cytotoxic

Dimensions

Active Area (cm²):	140
Total Electrode Size (mm):	165 x 133
Active Area Size (mm):	135 x 104

Electrical Properties (ANSI/AMMI DF-80)

Test	Specs	Value
AC Impedance 10 Hz (Ω)	< 3000	< 10
AC Impedance 30 kHz (Ω):	< 5	< 5
AC Large Signal Impedance (Ω):	< 3	2
Offset Instability and Internal Noise (µV):	< 100	< 4
Defibrillation Overload Recovery (mV):	< 400 (after 4") - < 300 (after 60")	< 50 - < 30
DC Offset Voltage (mV):	< 100	< 10
Bias Current Tolerance (mV):	< 100 (in 8 h)	< 1

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Manufactured by Telic S.A. - Spain

Description

To protect adult patients during defibrillation or cardioversion by means of a defibrillator equipped with reusable plates; ET3010 plates should be used.
This is a pair of single-use, anti-scalding pre-gelled adhesive plates suitable for use with any defibrillator equipped with reusable electrodes.
The perimeter support is made of waterproof foam with biocompatible acrylic adhesive. The corners are rounded and they are fully electrically insulated except the area covered by the conductive Hydrogel™.
The plates have passed all the tests required by the regulations and are biocompatible, non-irritant and stable.
The product is latex-free.
They are packed in quick-to-open bags to facilitate use during emergency operations.

Regulatory Information

Class IIb product according to Annex IX of MDD 93/42/EEC, rule 9.

46466/R - GMDN: 11500 - CND C020401