

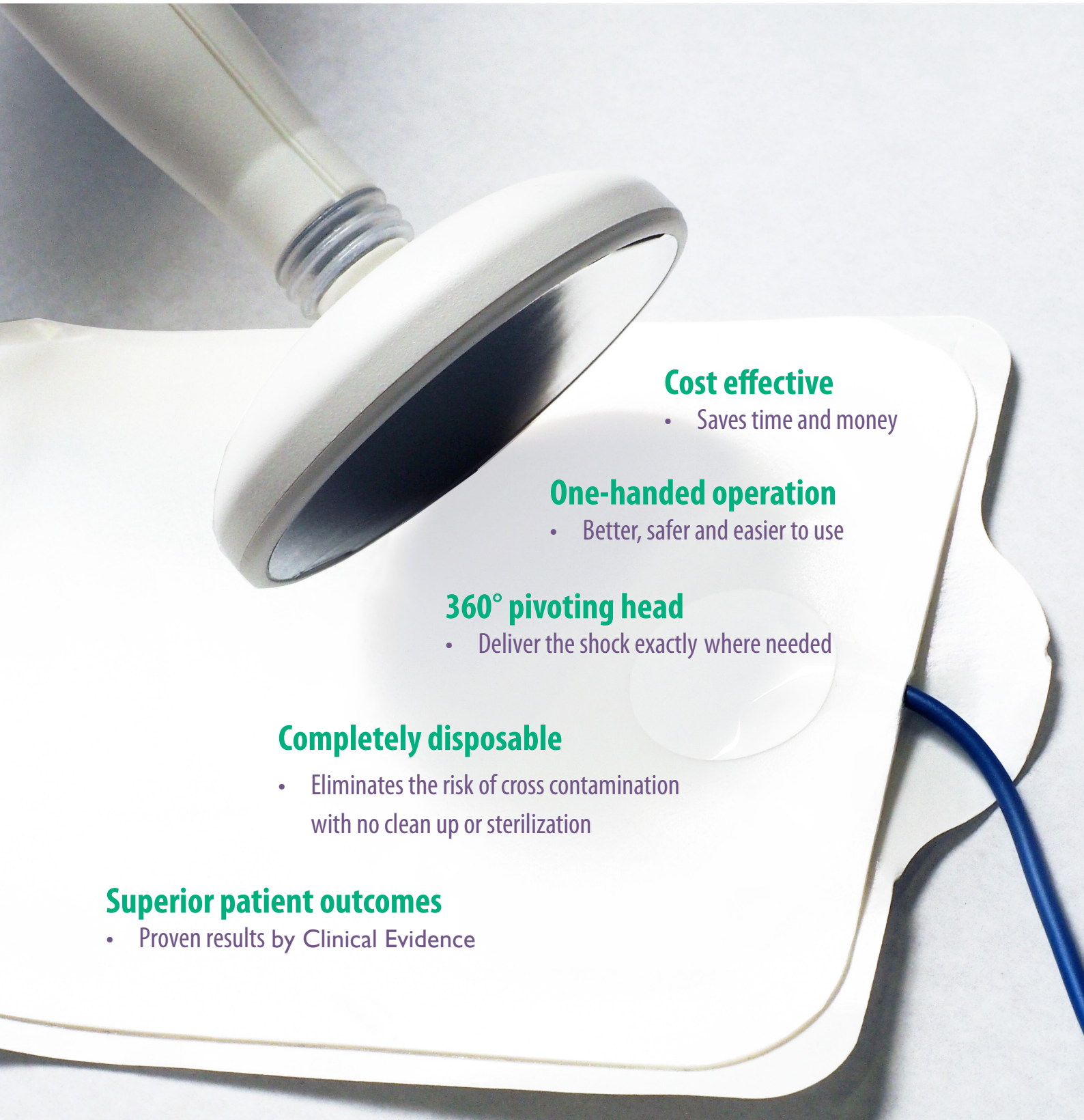


iD-System™

One-handed Disposable Sterile internal Defibrillation System

CE 2460

 **SMART**
Clinical Products



Cost effective

- Saves time and money

One-handed operation

- Better, safer and easier to use

360° pivoting head

- Deliver the shock exactly where needed

Completely disposable

- Eliminates the risk of cross contamination with no clean up or sterilization

Superior patient outcomes

- Proven results by Clinical Evidence

Institutional report on safety and efficacy

by prof. dr. P. Wouters, director cardiovascular anaesthesia, University Hospital Leuven,

"...The primary requirements of safety and efficacy being fulfilled..... the system shows a number of secondary properties that make it particularly attractive for use in cardiac surgery. In comparison to more conventional systems, 1) it can easily be used as a hybrid cardioversion system, 2) it consists of disposable materials (reducing the risk of disease transmission) and as mentioned previously, 3) its small size and single contact point approach permits safe use in limited access conditions such as with small-incision surgery and in redo surgery associated with extensive adhesions..."

by corresponding author and principal investigator: Dr. Maud Beran, Dept of Anaesthesiology & Intensive Care Medicine, ZOL Genk

"... it can be concluded that the iD-system defibrillator is safe, efficacious , reliable and user friendly, as a topical defibrillator in cardiac surgery. The flexible lightweight paddle was found easy to manipulate within a constrained area of the chest cavity and minimizes the risk for direct injury requiring only a single contact point with the ventricle. This contact point was deemed sufficient in 98% of the cases. System failure was not mentioned on any occasion. The adhesive pad on the patient's back, serving as the positive pole, did not cause harm to the skin. The iD-system defibrillator may also save costs of sterilization as the single paddle only needs to be opened when defibrillation is required..."

One-handed **SMART** operation

Better, Safer and Easier to use

Internal Defibrillation System (iD-System™)

The iD-System™ is designed for internal defibrillation in the same manner as the conventional internal paddles, which are used during intra-thoracic surgery. It delivers a shock to a patient's heart to restore normal sinus rhythm. The iD-System™ is compatible, through an iD-Smart Cable, with all main defibrillator/monitors which are currently available in the market.

The iD-System™ consist of three components:

1. The iD-Paddle™ is a disposable sterile one-handed paddle. The iD-Paddle™ (iD-1200 or iD-1300) is placed in contact with the heart when an actual shock is needed to restore normal sinus rhythm.
2. The iD-Electrode™ (iD-1100) is a disposable non-sterile electrode pad placed on the back of the patient and connected to the same defibrillator as the iD-Paddle™.
3. The iD-Smart Cable (iD-1500, iD-1510 or iD-1530) is a re-usable non-sterile cable that will connect the iD-Paddle and the iD-Electrode with your defibrillator.

Key Features

- One-handed operation – better, safer and easier to use.
- 360° Pivoting head – deliver the shock exactly where needed.
- Completely disposable – eliminates the risk of cross contamination. Superior patient outcomes – proven results in Clinical Studies.
- Cost effective – saves time and money. No sterilization process. Only open the pouch of the iD-Paddle™ when there is an actual shock needed.

Advantages

The iD-System offers real advantages over conventional reusable internal defibrillation spoons/paddles. The iD-System™ is beneficial to:

- OR staff who currently must maintain and handle defibrillation paddles before and after use.
- Patients, who are at risk of cross-contamination associated with any reusable, invasive surgical products.
- Biomedical engineers, whose responsibilities include testing, tracking and investigating failures of (sterilized) reusable paddles.

Models available

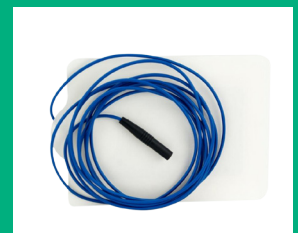
- iD-Electrode™ model iD-1100
- iD-Paddle™ "Large" model iD-1200 – Contact size 32 cm²
- iD-Paddle™ "Small" model iD-1300 – Contact size 9 cm² (in Q2-2024)
- iD-Smart Cable model iD-1500 Semi Finished Cable
- iD-Smart Cable model iD-1510 Physio/Strycker with Shock Button
- iD-Smart Cable model iD-1530 Philips DFM100 & Intrepid



iD-Paddle™ "Large" model iD-1200



iD-Paddle™ "Small" model iD-1300



iD-Electrode™ model iD-1100



iD-SMART Cable™; iD-1500



iD-SMART Cable™+ Shock button; iD-1510



iD-SMART Cable™; iD-1530

Technical information iD-System™

iD-Paddle™ Characteristics

- One-handed operation
- Single patient use
- Sterile, disposable, lightweight
- Model Size Large/Small
- Shelf life - 36 months unopened

iD-Paddle™ Dimensions

- Contact size: "Large" 32 cm² / "Small" 9 cm²
- Handle length 19.5 cm
- Handle diameter 8.5 cm
- Overall length 22.5 cm
- Weight: "Large" 0.111 kg / "Small" 0.0975 kg
- Cable Color Blue
- Cable length 3 meters
- Plug / Red square shroud 4mm

General

Meets applicable portions of the following standards:

- ANS/AAMI DF80: Medical electrical equipment
- EN ISO 10993-1: Biocompatibility
- EN60601-1: Med.Electrical Equipment, Gen.Req for Safety
- EN60601-1-2: Med.Electrical Equipment, Gen.Req for Safety
- EN60601-2-4: Particular Req for the Safety of Cardiac Defibs

Electrical Specifications: iD-System™ :

- Therapy energy range: up to 50 Joules
- To be used with the iD-Electrode™, Disposable External Pad
- Therapy waveform compatibility: monophasic or biphasic
- Peak Operating voltage: 1700 Volts
- Peak operating current: 85 Amps
- Maximum discharge rate: 1 minute duration – 6 cycles/min
- Service life : 20 cycles @ 50 Joules
- IEC Type : CF applied part

iD-Electrode™ Characteristics

- One electrode pad
- Single patient use
- NON sterile
- Model Sizes Adult /Pediatric and Baby
- Shelf life - 60 months unopened

iD-Electrode™ Dimensions

- Contact size: 110,5 cm²
- Overall size : 164,59 cm²
- Max. Energy : 200 joules
- Weight 0.069 kg
- Cable Color Blue
- Cable length 1,95 meters
- Plug / Black Round shroud 4mm

Environmental Specifications:

- Operating temperature: 0°C to 40°C (32°F to 104°F)
- Storage temperature: 5°C to 30°C (41°F to 86°F)
- Transport temperature: -20°C to +60°C (-4°F to +140°F) Maximum for 3 days
- Storage humidity: 15% to 85%
- Storage altitude: 0 to 4.57 km (0 to 15,000 ft.)
- Operating altitude: 0 to 4.57 km (0 to 15,000 ft.)
- Shock: no functional damage by 0.9 m (3ft.) drop
- Atmospheric Press.: 860hPa - 1060hPa

iD-Smart™ cables:

iD-1500:

- CU Medical Paramedic CU-ER5 & CU-HD1 Lifegain
- Mindray BeneHeart D3 & D6 Defibrillator
- Bexen R700 and R800
- Progetti Rescue Life Defibrillator
- ZOLL R series® and ZOLL M series®

iD-1510:

- Physio-Control LIFEPAK® 12 , 20(e) and 15

iD-1530:

- Philips Intrepid and DFM100



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