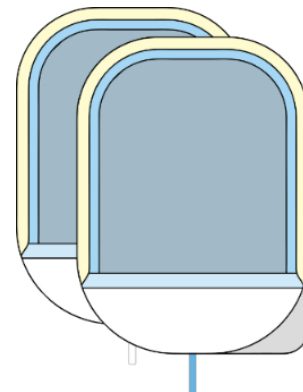


SKINTACT® Multifunction Radiolucent Electrodes for Adults/Pediatrics

(DF20N, DF20NC, DF20NCE, DF26N, DF27N, DF27NC, DF28N, DF28NC, DF43N)

KEY FEATURES

- Disposable, self-adhesive multifunction electrodes for adults/pediatrics for defibrillation, pacing, monitoring and cardioversion
- 100% Quality Control
- For up to 50 shocks (360J monophasic and biphasic)
- For up to 24 hours of monitoring
- For up to 1 hour of pacing using 140mA / 120ppM (pulse duration 20ms)
For up to 1 hour of pacing using 80mA / 100ppM (pulse duration 40ms)
- For up to 8 hours of pacing using 70mA / 60ppM (pulse duration 20ms)
For up to 8 hours of pacing using 50mA / 60ppM (pulse duration 40ms)
Inspection of pads every 30 minutes
- Radiolucent (Cable and riveting are visible on X-Ray)



PRODUCT	
Characteristics	disposable, pre-gelled self-adhesive, single use non sterile
Size	Adult/Pediatric
Shelf Life	36 months unopened pouch
Temperature conditions	min. / max.
Transport Pouch, max. 10 days	-40°C / +75°C
Storage Pouch	0°C / +50°C
Operating Pouch	0°C / +50°C

CLASSIFICATION	
Classification REG (EU) 2017/745, Annex VIII	Class I
Compliant with REG (EU) 2017/745	

PERFORMANCE	
IEC 60601-2-4	
ANSI/AAMI EC53	

BIOCOMPATIBILITY	
ISO 10993-1 seqq.	

ENVIRONMENTAL INFORMATION	
Compliant with RoHS Directive	
Compliant with REACH Regulation Information according to Art. 33 for substances contained above 0.1wt% (only DF20N, DF20NC, DF20NCE, DF28N, DF28NC)	Boric acid ¹
Not made with natural rubber latex	

PAD DIMENSIONS	
Electrode Shape	oval
Total Area [cm ²]	appr. 115
Adhesive Area [cm ²]	appr. 112
Gel Area / Active Area [cm ²]	appr. 80
Gel Thickness [mm]	0.80 / ± 0.10

MATERIALS PAD	
Carrier Material	Adhesive PE Foam
Conductive Material	Tin
Gel	Adhesive Hydrogel
Protective Cover	Siliconized PET Foil

ELECTRODE PACKAGING	
Pouch	1 Set (2 pads / pouch)
Lot number and expiration date on every pouch	
Electrode and connector are packaged within pouch (DF20N, DF26N, DF27N, DF28N, DF43N)	
Cable out-of-pouch electrodes are single packaged in a polybag (DF20NC, DF20NCE, DF27NC, DF28NC)	

MATERIALS PACKAGING	
Pouch	PET / Al / PE (PET Polyester, Al Aluminum, PE Polyethylene)

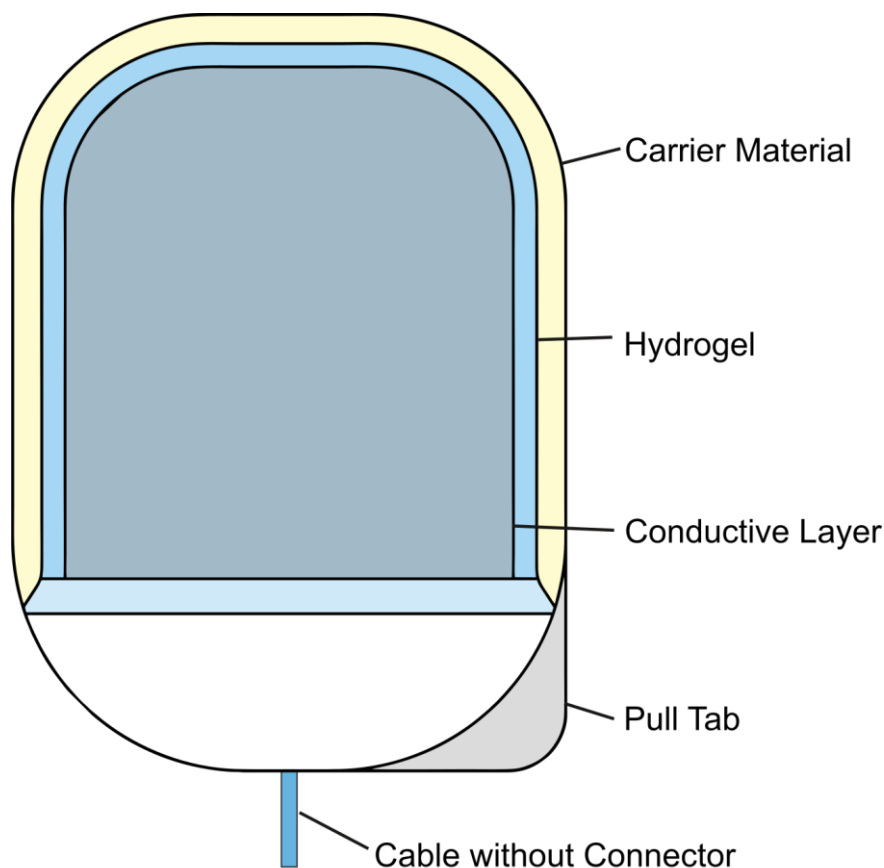
BOX / CARTON PACKAGING	
Pouches / Box	10 Pouches
Pouches / Carton	60 Pouches
One IFU within every box	

¹ Based on the information currently available, this substance does not pose any risk if the article is used as intended. Additional information is not necessary to allow safe use of the article.

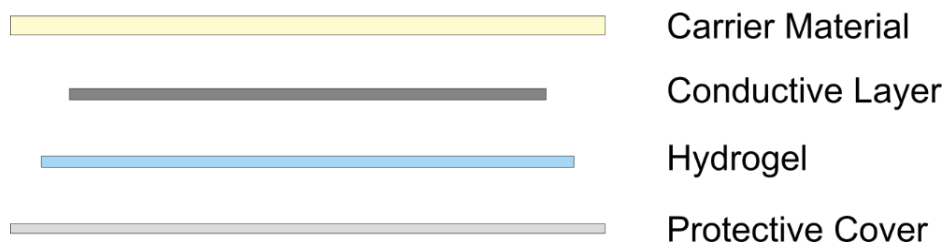
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SCHEMATIC TOP VIEW



SCHEMATIC CROSS SECTION

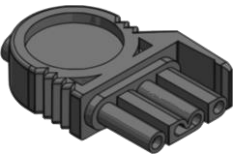
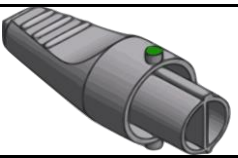
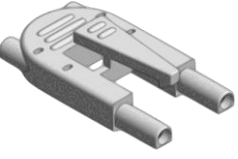
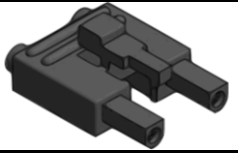


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ELECTRODE TYPES

SKINTACT® Multifunction Electrodes for Adult/Pediatrics are available for different defibrillators:

ELECTRODE TYPE	CONNECTOR	COMPATIBLE WITH FOLLOWING DEFIBRILLATORS	CABLE LENGTH
DF20N		Physio-Control Lifepak 12, 15, 20, 20e, 500 and 1000 Comen S1, S5 and S8	1.20m
DF20NC		Physio-Control Lifepak 12, 15, 20, 20e, 500 and 1000	1.20m preconnectable 0.45m cable out-of-pouch
DF20NCE			1.20m preconnectable 0.45m cable out-of-pouch
DF26N		With adapter cable M3507A: Philips HeartStart MRx, XL, XL+ Efficia DFM100 / Intrepid	1.20m
DF27N		Philips HeartStart FR2, FR2+ With adapter cable M3508A: Philips HeartStart MRx, XL, XL+ Efficia DFM100 / Intrepid	2.00m
DF27NC		With adapter cable M3507A and adapter 05-10200: Philips HeartStart MRx, XL, XL+ Efficia DFM100 / Intrepid Philips HeartStart FR3 (electrode self-test is not supported) Philips Heartstart FR2, FR2+ With adapter cable M3508A: Philips HeartStart MRx, XL, XL+ / Intrepid With adapter cable M3507A and adapter 05-10200: Philips HeartStart MRx, XL, XL+ / Intrepid Philips HeartStart FR3 (electrode self-test is not supported)	
DF28N		Zoll M, E, R and X Series With adapter cable 8000-0308-01/02, 8009-0749, 8300-0783, 8300-000676	1.20m
DF28NC			1.20m preconnectable 0.45m cable out-of-pouch
DF43N		Nihon Kohden TEC-5500, TEC-7600, TEC-7700 Series with pad adaptor JC-755V Nihon Kohden TEC-8300 Series with pad adaptor JC-855V	2.00m