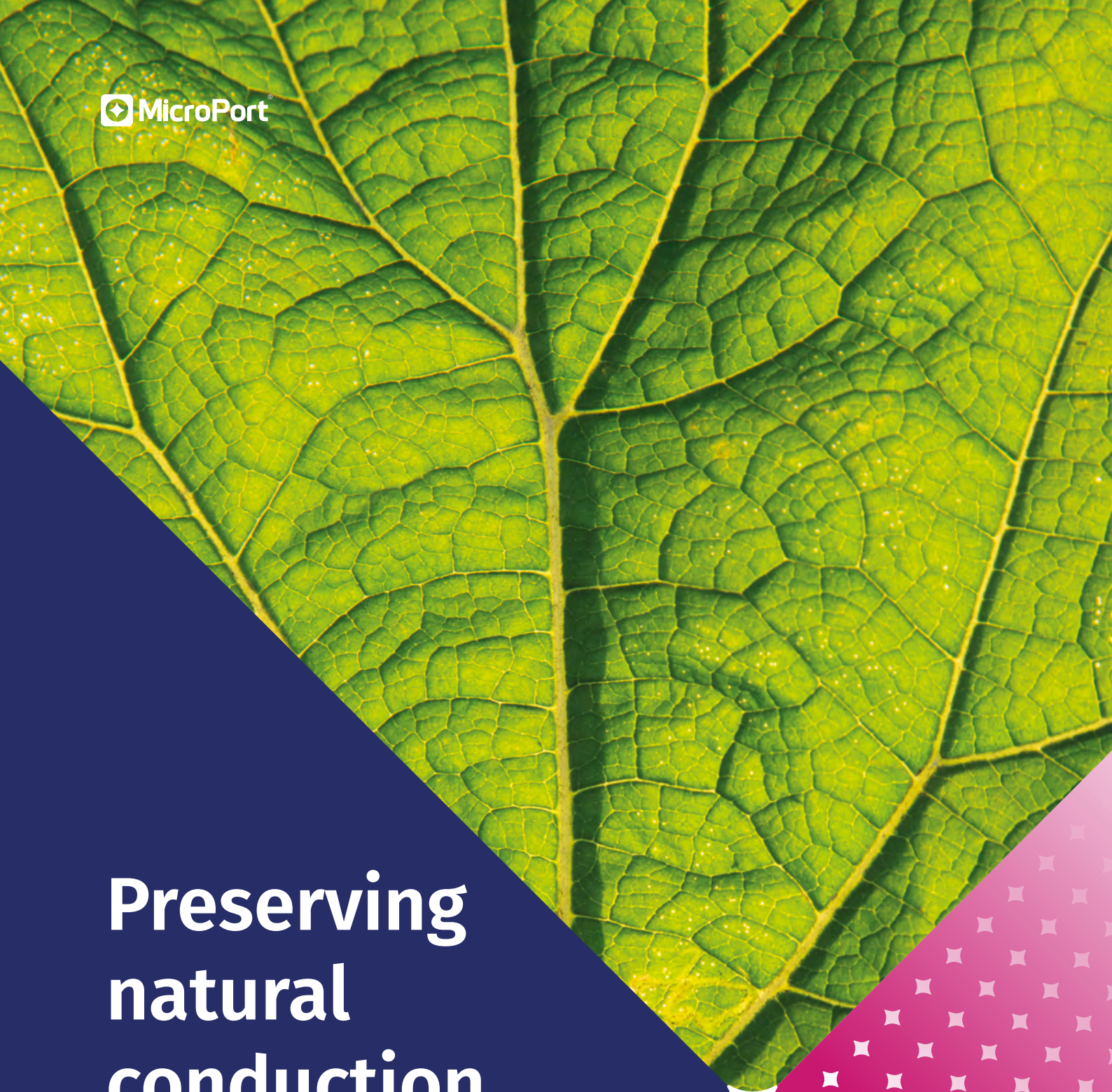
MicroPort®



Preserving natural conduction

SafeR™

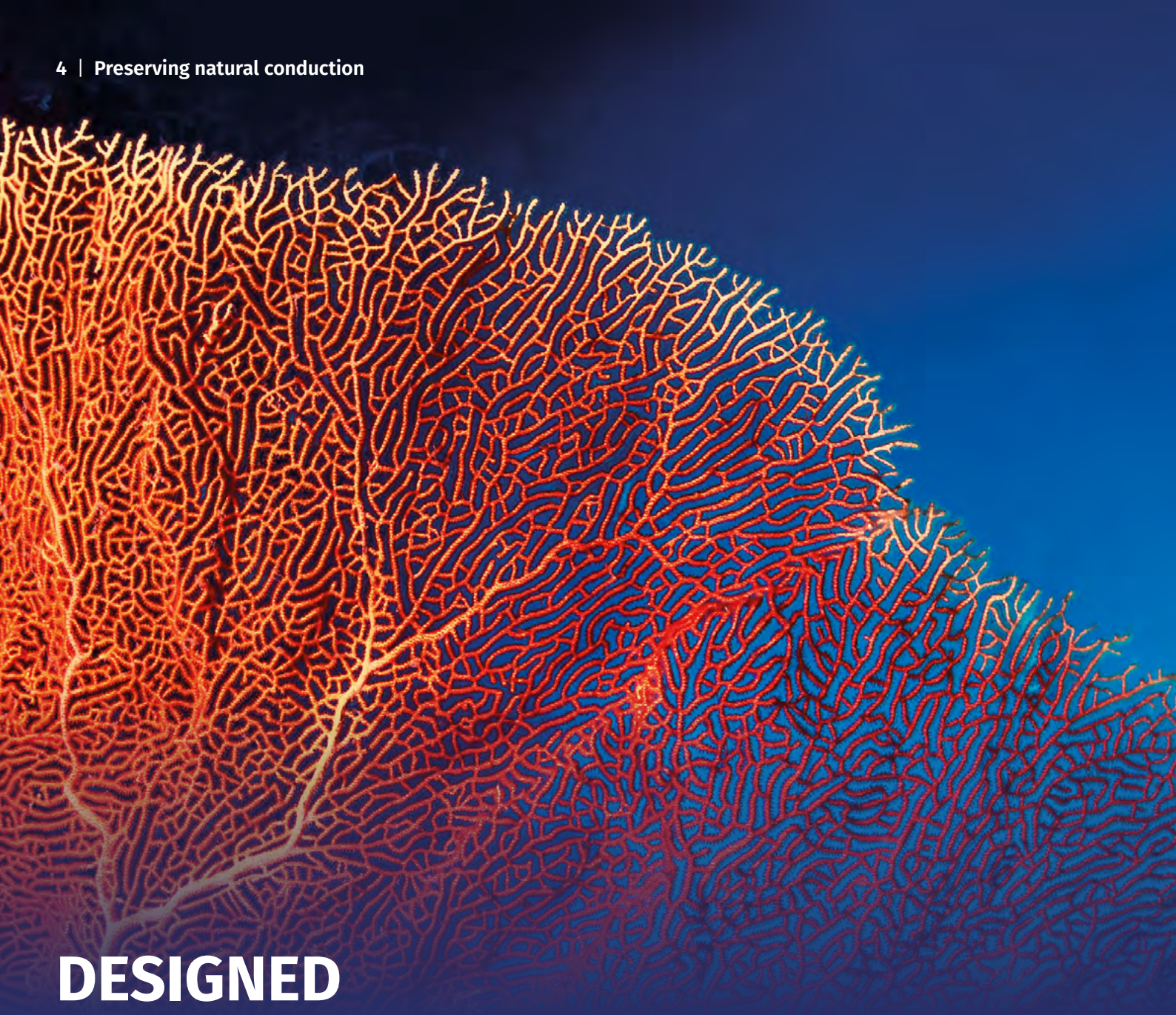
AV Management Algorithm

SafeR™

Preserving natural conduction

Beating for the past two decades, SafeR™ has stood as the sole clinically proven solution to drastically reduce ventricular pacing, promoting natural AV conduction whilst ensuring long-term safety and efficacy for you and your patients[1].

SafeR™, powered by exclusive technology, is a unique and versatile algorithm that offers the freedom to create personalized therapies for both SND and AVB patients while safeguarding spontaneous AV conduction, leading to an extended device longevity[2].



DESIGNED FOR ALL PATIENTS

SafeR™ was the first algorithm that provided a solution to unnecessary pacing and promote natural AV conduction[1]

SINCE

20

YEARS

- **AAI PACING** whilst continuously monitoring AV conduction
- **SWITCH TO DDD** pacing when needed for all types of AV block, at rest and exercise
- **BACK TO AAI** mode when needed

SafeR™

is designed for all pacemakers patients, managing all types of AV block, including first AV block responding to both rest and exercise

SND AVB I-II-III

MANAGES ALL TYPES OF AVB

Switch criteria from AAI **to DDD mode**		Switch criteria from DDD **to AAI mode**	
2 CONSECUTIVE BLOCKED ATRIAL EVENTS	AVB III	12 CONSECUTIVE SENSED R WAVES	AAI
3 BLOCKED ATRIAL EVENTS/ 12 CONSECUTIVE CYCLES	AVB II	EVERY 100 PACED CYCLES	AAI
6 CONSECUTIVE LONG PR INTERVALS	AVB I	EVERY MORNING AT 8:00 AM	AAI
VENTRICULAR PAUSE OF 2, 3 OR 4 SECONDS (PROGRAMMABLE)	PAUSE		

LONG PR

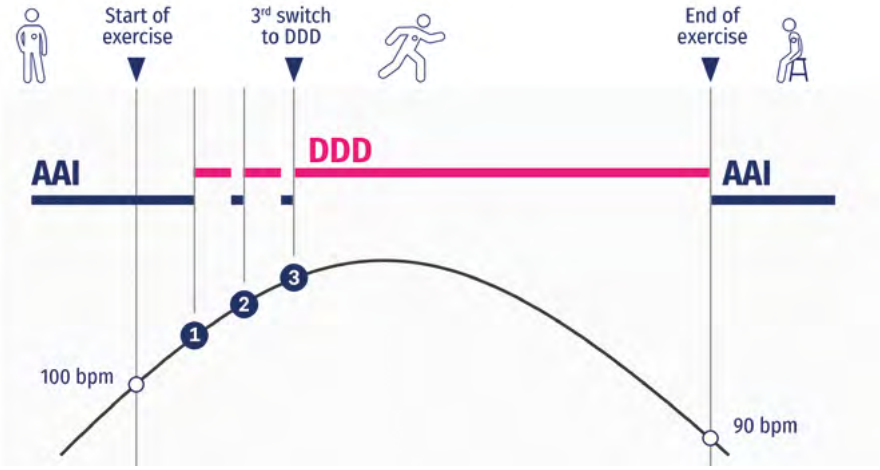
WITH A UNIQUE MANAGEMENT OF LONG PR

Personalised long PR parameters at rest & exercise

Automatic adaptation of long PR Intervals depending on heart rate in order to mimic physiological PR interval variability

HEMODYNAMIC SUPPORT DURING EXERCISE

SafeR™ provides pacing support in the event of AV Block experienced during exercise



OFFERS FULL DIAGNOSTICS WITH A & V EGMs

Records episodes of **AV block with EGM A & V**

Provides an accurate **AVB degree classification** allowing for optimized patient treatment

CLINICALLY PROVEN

The ANSWER study[1]

Randomized controlled multicentre trial assessing SafeR™ mode versus standard DDD mode in sinus node disease (SND) or AV block (AVB) patients. ANSWER enrolled 650 patients (52% SND, 48% AVB) at 43 European centers and randomized in SafeR or DDD, followed for 36 months.

43
European centers

650
patients enrolled
SND (52%) & AVB (48%)

Randomized
- **SafeR™ mode** (n=314)
- **DDD mode** (n=318)

SafeR™

promotes natural AV conduction and is proven to be safe and effective for both AVB and SND patients[1,2]

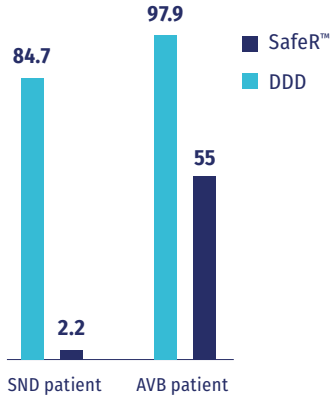
SAFER™ PRESERVES THE NATURAL CONDUCTION FOR BOTH SND AND AVB PATIENTS[2]

Excessive right ventricular pacing may lead to deleterious effects[3]

SafeR™ significantly increases the spontaneous V contraction percentage for all patients compared to DDD after 3 years follow-up

NATURAL AV CONDUCTION EXCEPTIONNALLY ENHANCED FOR SND PATIENT

SafeR™ IS ALSO VERY EFFECTIVE FOR AVB PATIENTS



% of ventricular pacing DDD VS SAFER™ after 3 years follow-up

SAFER™ IS ASSOCIATED WITH SIGNIFICANT RISK REDUCTIONS[1]

51%

RISK REDUCTION OF CARDIAC DEATH OR HOSPITALIZATION
and 30% risk reduction in cardiovascular hospitalizations for SND & AV block patients[1]

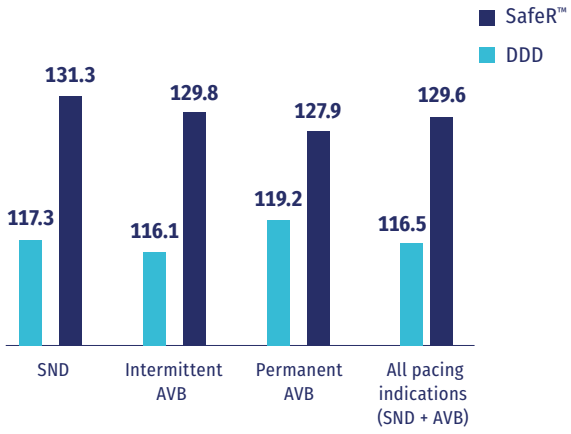
35%

RISK REDUCTION OF FIRST AF ONSET IN AV BLOCK PATIENTS[4]
and by 23% in all patients[5]

SAFER™ EXTENDS DEVICE LONGEVITY[2]

VP reduction by SafeR™ translates into prolongation of estimated device longevity for all patients, including permanent and intermittent AVB patients and SND patients

MORE THAN 1 YEAR DEVICE LONGEVITY GAIN WITH SAFER™



Projected longevity gain of DDD vs SAFER™ mode
- in months -

MicroPort®

microport.com

ENO™ & TEO™

ALIZEA™ & BOREA™

TALENTIA™ & ENERGYA™

Available in our pacemakers and defibrillators

Learn more about our
SafeR™ technology

References
1- Stockburger M. et al; Long-term clinical effects of ventricular pacing reduction with a changeover mode to minimize ventricular pacing in a general pacemaker population; Eur Heart J. 2015 Jan 14; 36(3): 151–157.
2- Stockburger M. et al. Safety and efficiency of ventricular pacing prevention with an AAI-DDD changeover mode in patients with sinus node disease or atrioventricular block: impact on battery longevity-a sub-study of the ANSWER trial; Europace. 2016 May; 18(5): 739–746
3- Sweeney MO, Hellkamp AS, Ellenbogen KA, Greenspon AJ, Freedman RA, Lee KL, Lamas GA; MOde Selection Trial Investigators. Adverse effect of ventricular pacing on heart failure and atrial fibrillation among patients with normal baseline QRS duration in a clinical trial of pacemaker therapy for sinus node dysfunction. Circulation. 2003 Jun 17;107(23):2932-7. doi: 10.1161/01.CIR.0000072769.17295.B1. Epub 2003 Jun 2. PMID: 12782566.
4- Fauchier L, Boveda S, Moreno J at al. SafeR is associated with a risk reduction of first–onset AF in patients with Atrio ventricular blocks_ result from the ANSWER study. Abstract submitted for Cardiostim 2016.
5- Stockburger M; Defaye P, Boveda S et al. Minimized ventricular pacing delays first onset of AF in pacemaker patients without AF history. ANSWER post-hoc analysis. Abstract. European Heart Journal, Volume 36, Issue suppl_1, August 2015

Refer to user manual for complete instructions for use available at microportmanuals.com.

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BY MicroPort CRM

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