

CARDIAWAVE

Des ultrasons pour soigner la
sténose aortique



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126 years of combined experience in medical device and Life Sciences

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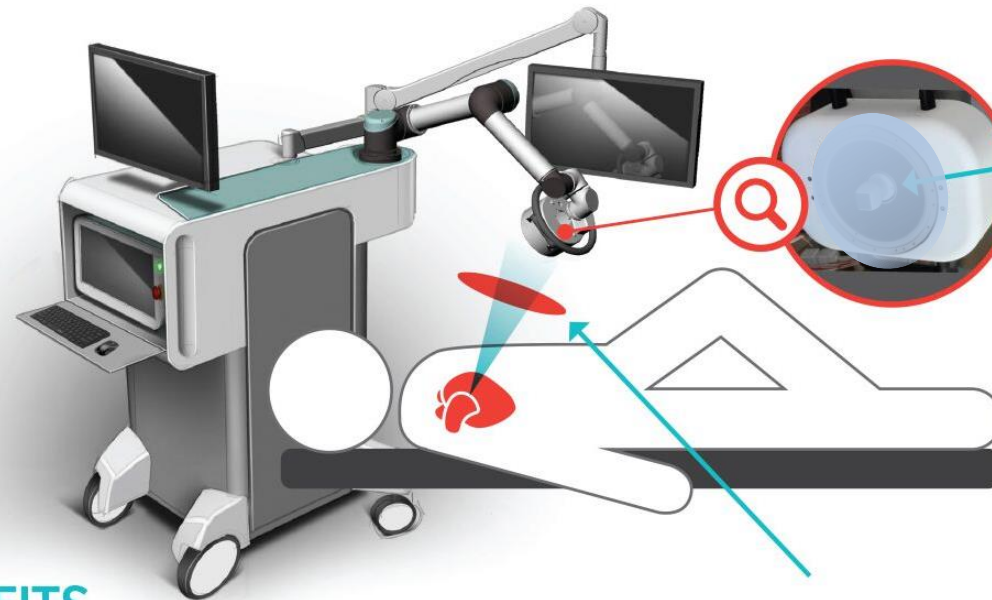




VALVOSOFT DEVICE: STATE-OF-THE-ART REAL-TIME IMAGING & THERAPEUTIC DEVICE



The **Valvosoft platform** includes therapeutical ultrasound generator and amplifier, an imaging system, an applicator, a support arm to position the applicator, touch-sensitive screen, software, etc.



The **applicator** with imaging probe to visualize in real time the aortic valve leaflets and with therapeutic ultrasound transducer

✓ BENEFITS

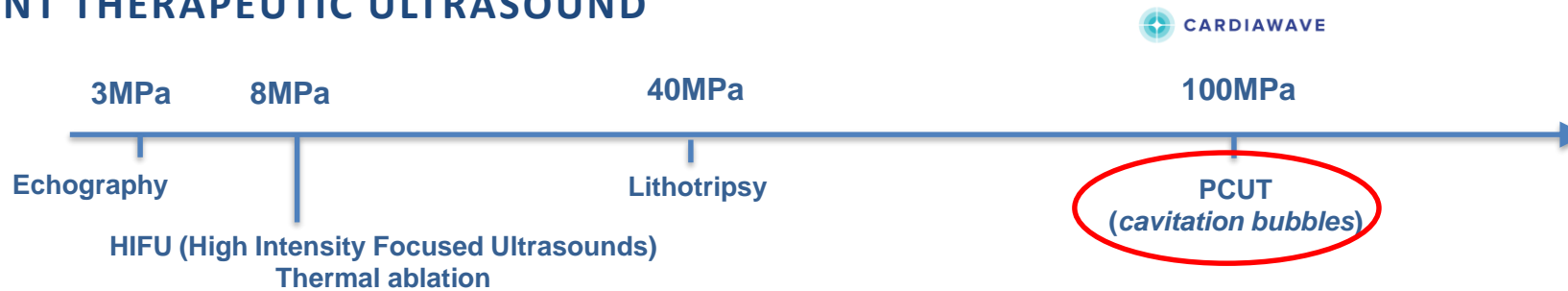
- Non-invasive
- Painless
- Immediate effect
- Ambulatory
- Can be repeated when required




The **conductive pouch** paired with the patient and critical to enable propagation of therapeutical ultrasounds and image quality.



DIFFERENT THERAPEUTIC ULTRASOUND

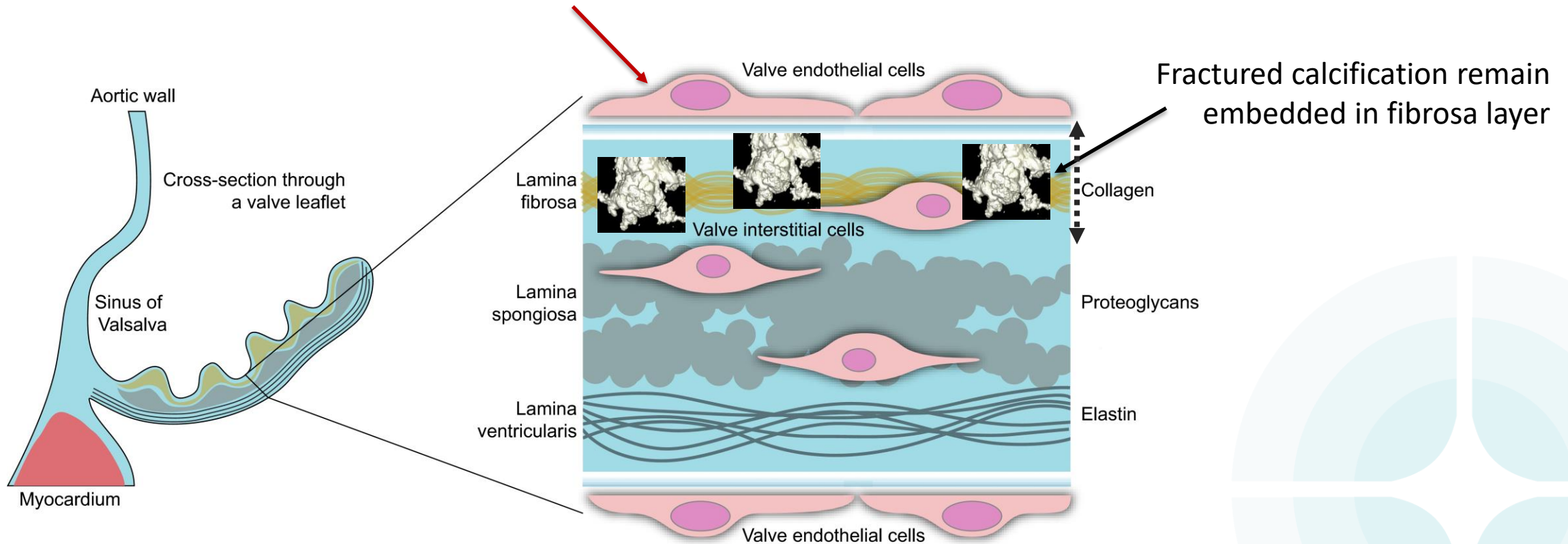


	 CARDIAWAVE	Lithotripsy	HIFU
Cardiac noninvasiveness (<i>in depth</i>)	+	-	-
Preservation of tissue through which ultrasounds passes (<i>very short pulses</i>)	+	+	-
(Real-time) moving focal point	+	-	-
Therapeutical energy	Mechanical	Mechanical	Heat
Therapeutical effect	Tissue softening	Break up of stone	Tissue ablation by coagulation necrosis



AORTIC STENOSIS: CALCIFICATION EMBEDDED IN THE LEAFLET TISSUE OF THE AORTIC VALVE

With Valvofsoft, no hole or damage to the tissue (endothelial cells and fibrosa)





VALVOSOFT ≠ CAVITRON

Cathet Cardiovasc Diagn. 1991 Sep;24(1):16-21.

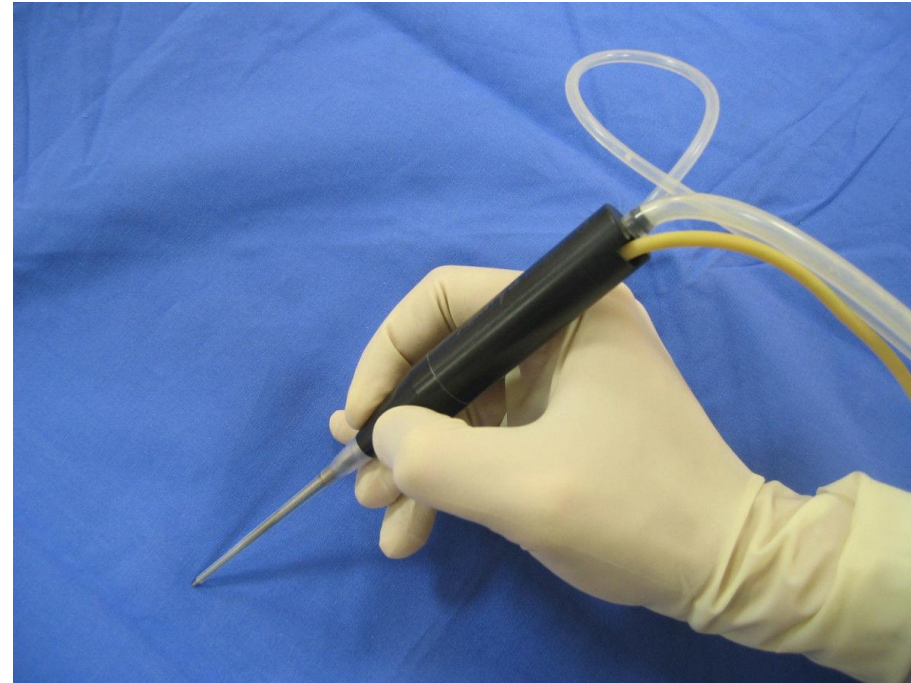
Surgical aortic valvuloplasty using the Cavitron Ultrasonic Surgical Aspirator: an invasive hemodynamic follow-up study.

Leithe ME¹, Harrison JK, Davidson CJ, Rankin JS, Pierce C, Kisslo KB, Bashore TM.

Eur J Cardiothorac Surg. 1996;10(7):498-504.

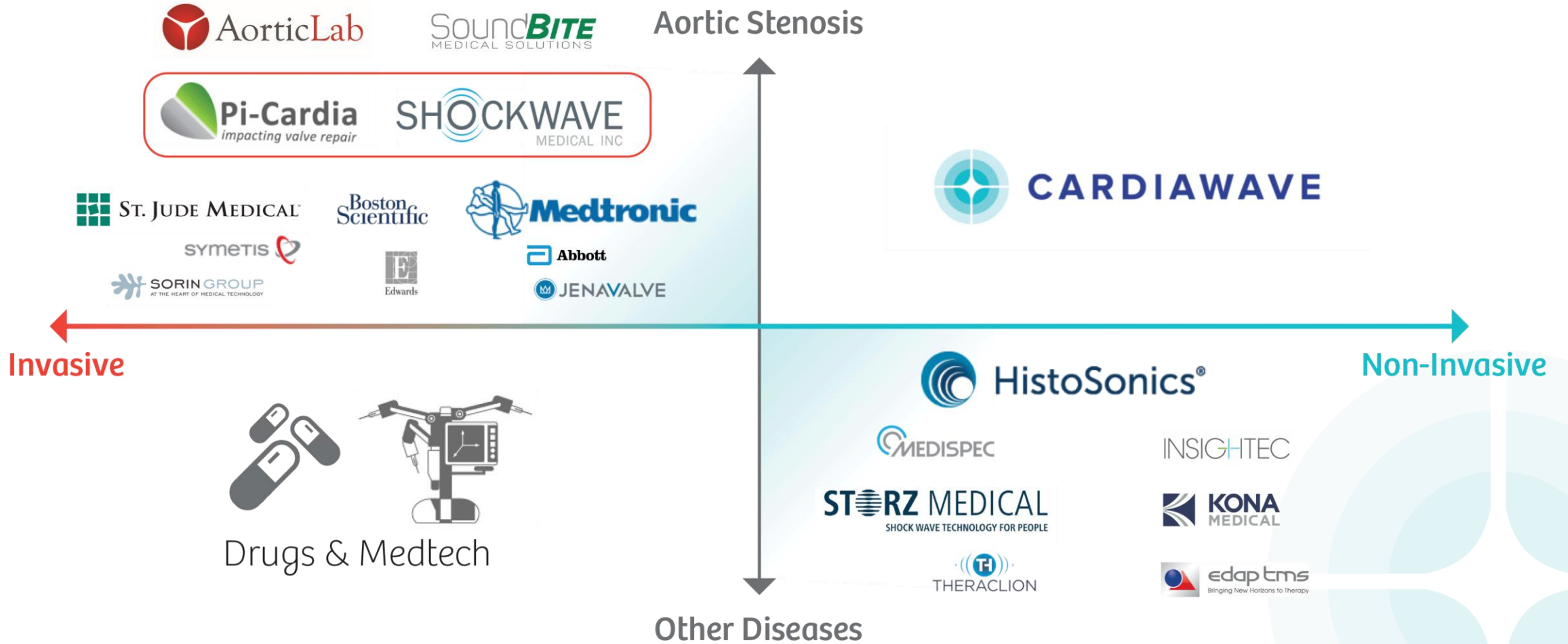
Aortic valve debridement by ultrasonic surgical aspirator in degenerative, aortic valve stenosis: follow-up with Doppler echocardiography.

Kellner HJ¹, Pracki P, Hildebrandt A, Binner C, Eisele G, Struck E.





COMPETITION





VALUE PROPOSITION



**EXTENDING
CURRENT INDICATION**



**PREVENTIVE
TREATMENT**



NON-INVASIVE



**LOWER RISKS
& COMPLICATIONS**



AMBULATORY



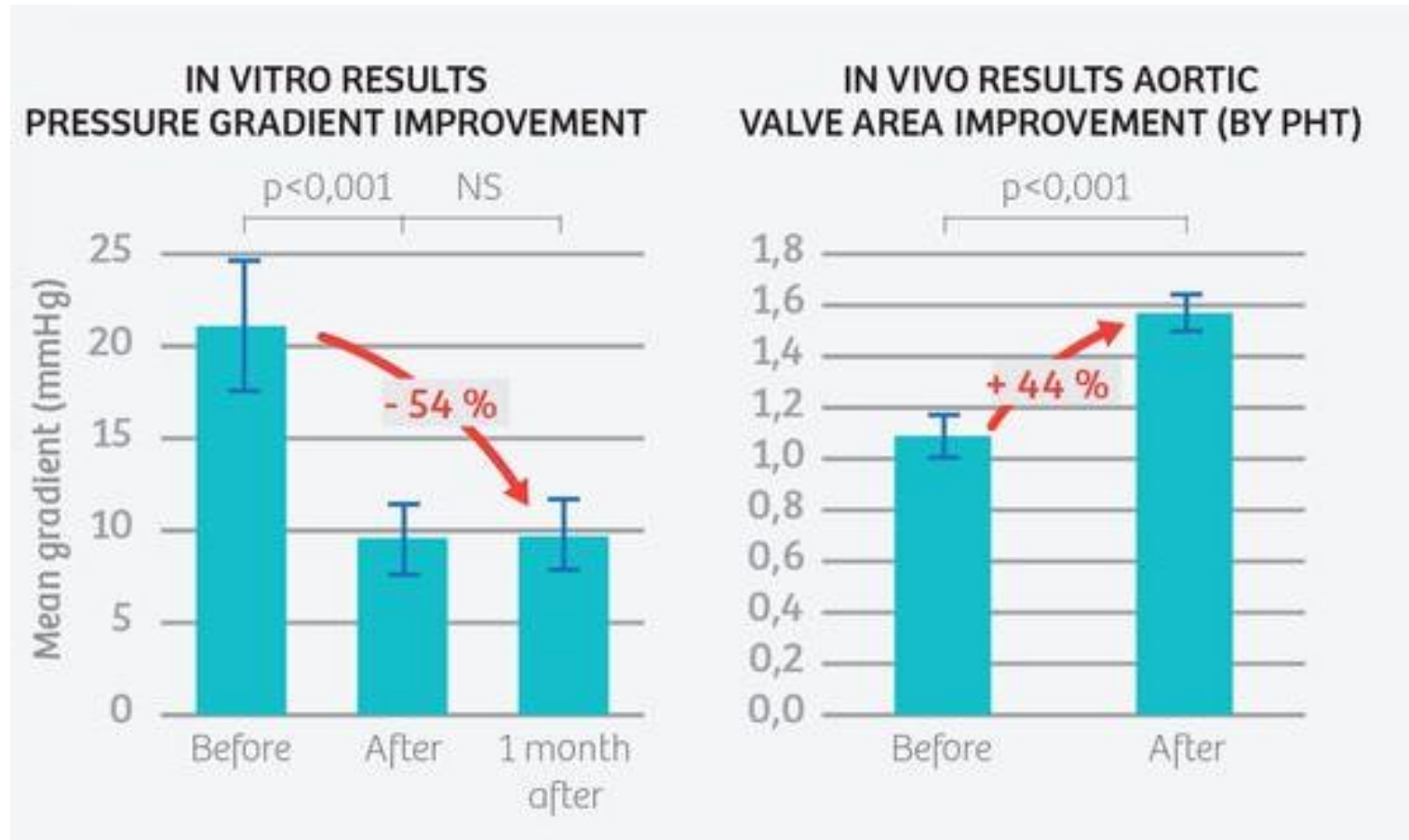
COST DECREASE



**QUALITY OF LIFE
IMPROVEMENT**



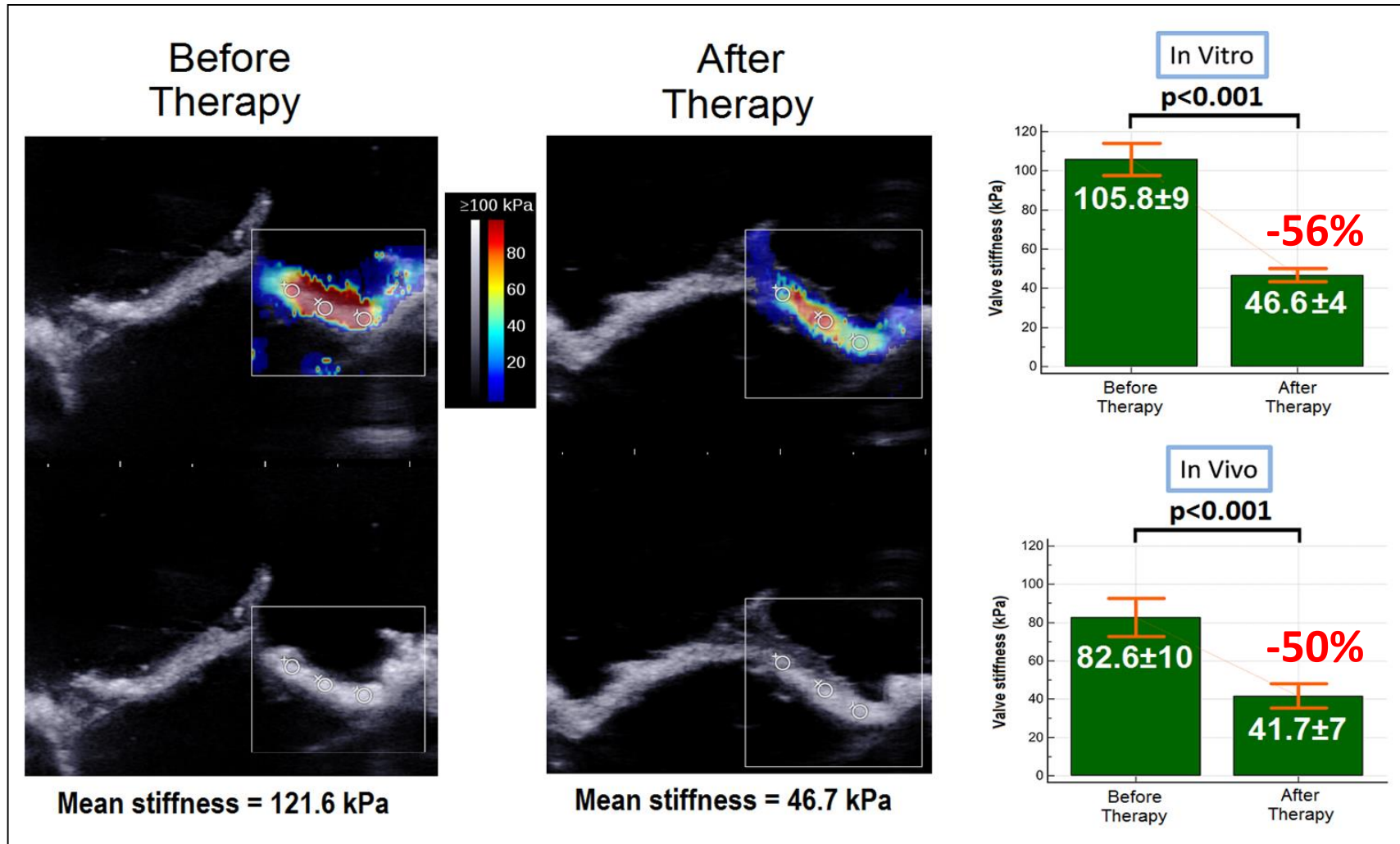
INITIAL PRECLINICAL VALIDATION – EFFICACY ON BIOPROSTHESIS IN VITRO & IN VIVO



Villemain O, Robin J, Bel A, Kwiecinski W, Bruneval P, Arnal B, Rémond M, Tanter M, Messas E, Pernot M. Pulsed Cavitation Ultrasound Softening. *JACC Basic to Transl Sci* 2017;2:372–83.



BIOPROSTHESIS SOFTENING MEASURED BY ELASTOGRAPHY



Villemain O, Robin J, Bel A, Kwiecinski W, Bruneval P, Arnal B, Rémond M, Tanter M, Messas E, Pernot M. Pulsed Cavitation Ultrasound Softening. *JACC Basic to Transl Sci* 2017;2:372–83.



PRECLINICAL VALIDATION – NO ANIMAL MODEL

Simulation, bench tests (human valves, bioprosthesis, pericardium) & in vivo (swines, sheeps & rabbits)



SAFETY

- No large debris, tiny particulates
- No tissue perforation (histology)
- No acute stroke
- No heart failure
- No aortic regurgitation

EFFICACY

- Statistically significant modification of key parameters:
- Pressure gradient decreased by half
 - Wider opening of the valve area $>1.5\text{cm}^2$
 - Reduction in stiffness by half



Prospective, controlled, multicenter, single arm clinical investigation.

Up to ten (10) subjects with severe symptomatic aortic valve stenosis **not eligible to TAVR/SAVR** according to local Heart Team.

Follow up period: 24 months.

Safety objective:

Assessment of procedure related mortality up to **30 days** post-procedure.

Performance objective:

Demonstration of the ability of Valvosoft to modify the structure of the calcified valve leaflets to improve their mobility immediately post-procedure compared to baseline.



INNOVER DANS LE SECTEUR DU DISPOSITIF MEDICAL : FACTEURS CLÉS DE SUCCÈS

- Un besoin médical
- Une technologie protégée
- Une équipe expérimentée et pluridisciplinaire
- Stratégies clinique et réglementaire claires
- Formation et proctoring
- Passage réussi de la R&D à l'industrialisation
- Modèle économique viable
- Stratégie d'accès au marché
- Cycle de développement long dans un nouvel environnement réglementaire
- Financements sur un temps long