How heart failure patients benefit from atrial shunts

Occlutech Atrial Flow Regulator (AFR)
The shunt allows the controlled blood flow from the left to the right atrium. The ensuing left atrial decompression is expected to improve symptoms, exercise tolerance and quality of life.

PRELIEVE
1-YEAR
RESULTS

INDICATIONS AND AREA OF APPLICATION: The use of the Occlutech AFR is meant to guard and secure the result of a balloon atrial septostomy (BAS), i.e. the atrial septal opening, which has been created in the following patient groups: a) Heart Failure patients with reduced ejection fraction (HFrEF) b) Heart Failure patients with preserved ejection fraction (HFpEF).

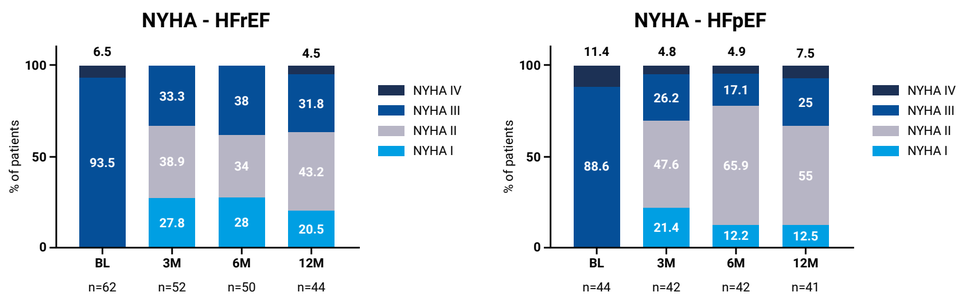
Occlutech

Clinically proven outcomes

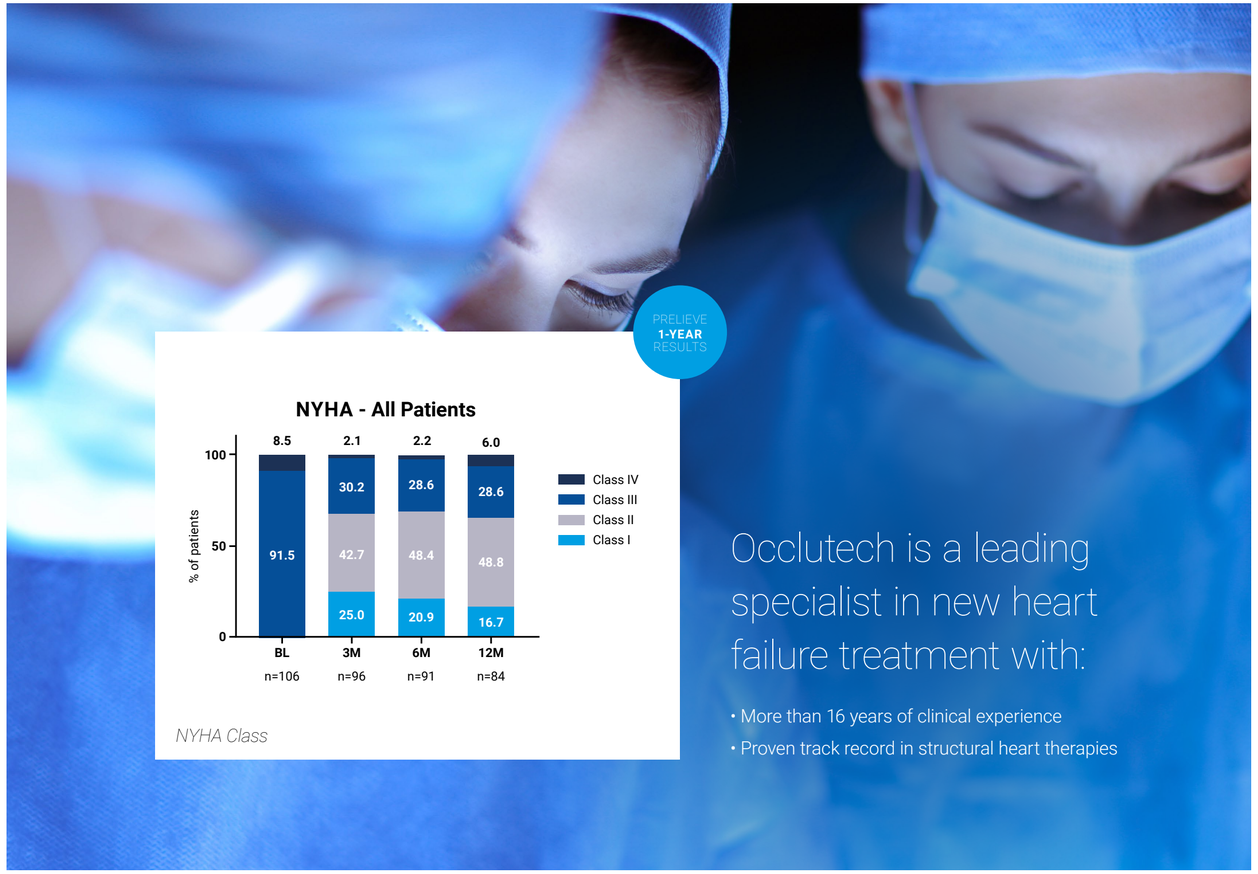
PRELIEVE is a prospective, non-randomized, multicenter study which enrolled both HFrEF and HFpEF patients with NYHA ≥ III and pulmonary wedge pressure ≥ 15 mmHg at rest (AFR 8 mm shunt device) or ≥ 25 mmHg during exercise (AFR 10 mm shunt device).

Overall, 67% of all patients improved in NYHA class

Study highlights

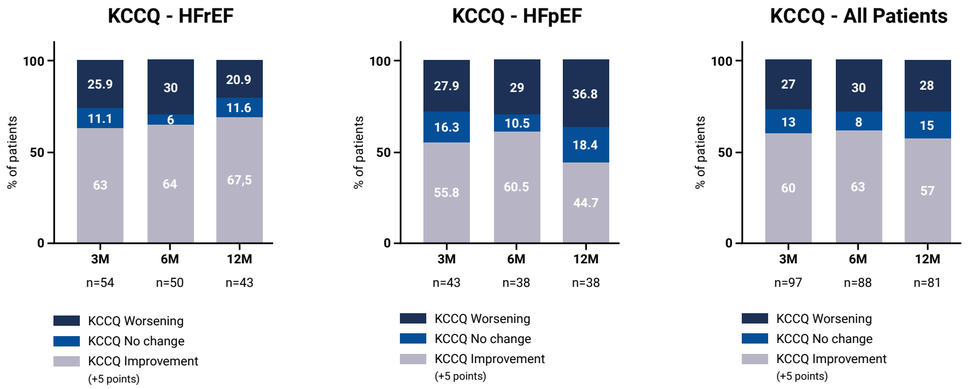


NYHA Class



NYHA Class

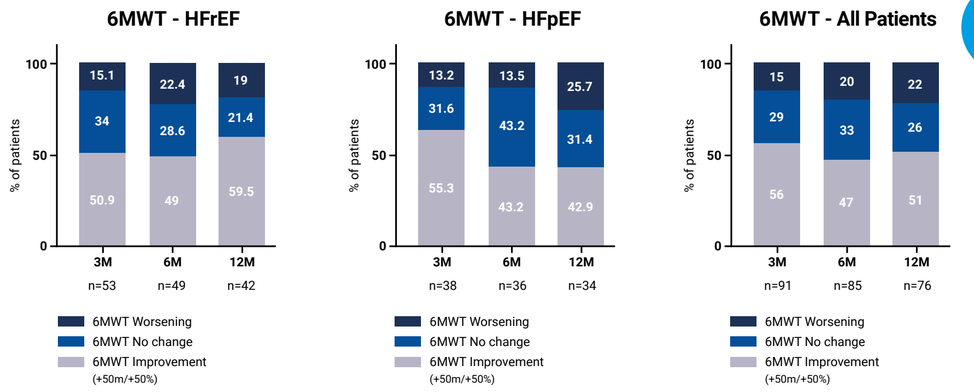
Overall, 57% of all patients had improved KCCQ scores (≥5 points) Study highlights



PRELIEVE **1-YEAR** RESULTS

Quality of life Kansas City Cardiomyopathy Questionnaire (KCCQ-12) overall summary score

Overall, 51% of all patients improved in 6MWT (≥50m) Study highlights



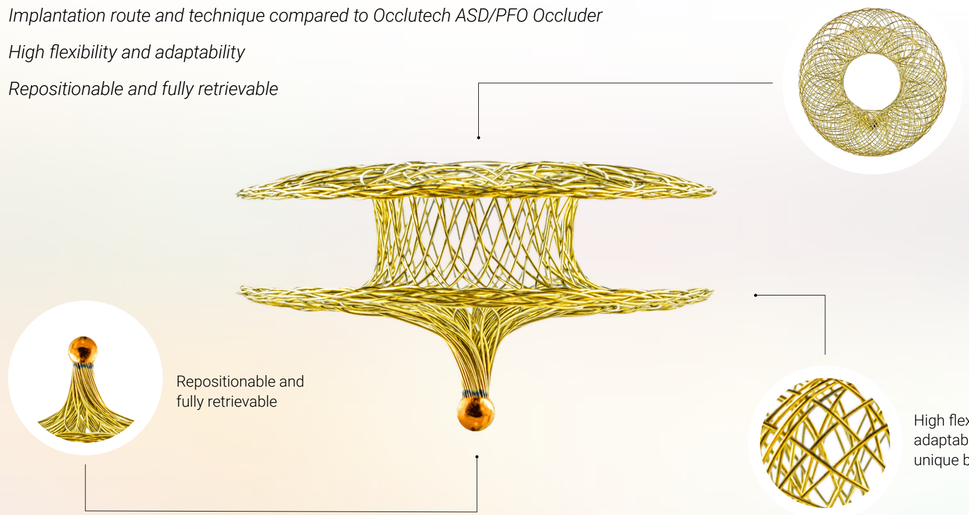
PRELIEVE **1-YEAR** RESULTS

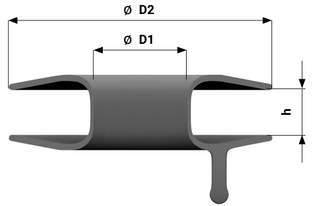
6 minute walking test (6MWT)

Well known platform paired with unique device

Developed for using its state-of-the-art Nitinol braiding technology in over 16 years of clinical experience.

- *Implantation route and technique compared to Occlutech ASD/PFO Occluder*
- *High flexibility and adaptability*
- *Repositionable and fully retrievable*





Ø D1: Diameter of the atrial septal fenestration
Ø D2: Diameter of both discs
h: Height

					Pusher System Item No**	
Occlutech AFR REF NO	**D1 [mm]**	**D2 [mm]**	**h [mm]**	**Occlutech Delivery Set (ODS) Size***	**Flex Pusher II REF. number**	**Pistol Pusher REF. number**
65AFR08M	8	21	5	12F (51DS012)	51FP120 (yellow)	55PP165 (yellow)
65AFR10M	10	23	5	14F (51DS014)	51FP120 (yellow)	55PP165 (yellow)
65AFR08L	8	21	10	12F (51DS012)	51FP120 (yellow)	55PP165 (yellow)
65AFR10L	10	23	10	14F (51DS014)	51FP120 (yellow)	55PP165 (yellow)

* Occlutech Delivery Set 45° (80 cm)
** Occlutech AFR is compatible with both Flex Pusher II and Occlutech Pistol Pusher, appropriate pusher is provided in the Procedure Pack with the device by Occlutech

Summary

AFR shunt therapy is safe:

- *no difference between 8 and 10mm shunt size in safety*
- *no increase in stroke/TIA*
- *no significant change in RV diameter and no RV failure*

Efficacy:

- *Device patency demonstrated in all patients*
- *2/3 of patients experienced a benefit in at least one of the functional end-points*

Notes

IMPORTANT SAFETY INFORMATION

INDICATIONS AND AREA OF APPLICATION
The use of the Occlutech AFR is meant to guard and secure the result of a balloon atrial septostomy (BAS), i.e. the atrial septal opening, which has been created in the following patient groups:
a) Heart Failure patients with reduced ejection fraction (HFrEF)
b) Heart Failure patients with preserved ejection fraction (HFpEF)

CONTRAINDICATIONS
The Occlutech AFR is contraindicated for the following:
• Any condition that, in the opinion of the physician, might interfere with the implantation or affect the patient's well-being thereafter
• Patients with sepsis (local or generalized) or acute infection(s)
• Patients with allergy to anti-platelet, anti-coagulant or anti-thrombotic therapy
• Patients with allergy to nickel and/or titanium and/or nickel/titanium-based materials (relative contraindication).

WARNINGS
The Occlutech AFR must be implanted exclusively by physicians trained in its use and who are experienced with interventional transcatheter techniques, including performing transseptal punctures and/or balloon atrial septostomy (BAS). After transseptal punctures and/or BAS, patients must be in stable conditions before implanting the Occlutech AFR.

For the Occlutech AFR
• The Occlutech AFR is to be used exclusively in accordance with this Instructions for Use (IFU) and its implantation is to be carried out as described in this IFU. 5
• Use of the Occlutech AFR is not recommended if the atrial septal thickness is larger than 10 mm.
• The user shall inspect all packaging and labels of this product before opening and follow the sub-sequential instructions.
• The user shall not use this product or any of its components if a Tyvek pouch seal appears damaged (contents may not be sterile); the label appears marked with text or symbols other than those on the label shown in the IFU; the label is illegible, inappropriate, or absent.
• The physician shall not use this product or any of its components after the "use by" (expiration) date.

The Occlutech AFR is intended for single use only and this medical device is not suitable for re-sterilization. As soon as the sterile seal of the device is broken, it is contaminated. Re-use or re-sterilization may compromise the structural integrity of the devices, lead to device failure, and result in patient injury, illness or death.

• This product is intended for single-use only, and the Occlutech AFR is not suitable for re-sterilization. Individual components of this product are made from a number of different and complex materials. The properties and performance of these materials could be negatively impacted by re-sterilization.
• Blood or its components have a high affinity to the materials used to manufacture this product. After the Occlutech AFR, the pusher, or the ODS have been in contact with blood, or its components, it is not possible to sufficiently remove blood, or its components, and the user shall select a new Occlutech AFR and pusher.

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION
Non-clinical testing demonstrated that the AFR is MR Conditional. A patient with this device can be scanned safely in an MR under the following conditions:
• Static magnetic field of 1.5-Tesla and 3-Tesla, only
• Maximum spatial gradient magnetic field of 3,000-gauss/cm (30-T/m) (extrapolated)
• Maximum MR system reported; whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode Under the scan conditions defined, the AFR is expected to produce a maximum temperature rise of 1.9°C after 15 minutes of continuous scanning (i.e., per pulse sequence).
Artifact information in non-clinical testing, the image artifact caused by the AFR extends approximately 5 mm from this implant when imaged using a gradient echo pulse sequence and a 3 Tesla MR system.

POTENTIAL ADVERSE EVENTS
Adverse events that may occur and may be procedure-related as well as device-related during or after a procedure include, but are not limited to: air embolism, allergic reactions, anesthesia reactions, apnea, arrhythmias, AV-fistula, bleeding (hemorrhage) requiring treatment, cardiac / vascular perforation, cardiac tamponade, death, device dislocation, embolization (of the implant, periprocedural and post-procedural), entrapment of pacemaker, esophageal injury, re-intervention or surgical intervention, femoral access complication requiring vascular surgery, hematoma, Infection, including endocarditis, pacing device malfunction, valve dysfunction or difficulty to exchange pacing lead associated with pacing lead entrapment, pericardial effusion (requiring interventions), pericarditis, perforations of vessels or myocardium, post pericardiotomy syndrome (PPS), pseudoaneurysm, pulmonary edema, seizure, severe desaturation and acute decompensation, stroke or transient ischemic attack (TIA), thrombus formation on the device, thrombosis, tissue erosion, vascular access site injury, vomiting.

Reference: Bergmann M.W. et al PRELIEVE - The Occlutech AFR: Matching shunt lenght and diameter to the patient, THT 2023

CAUTION: This product is intended for use by a physician. Prior to use, read the Instruction for Use, for more detailed information on indications, contraindications, warnings, precaution and adverse events.

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