

# MiCardia Corporation's en *Cor*<sub>SQ</sub> Mitral Valve Repair System™ Presented During the "Mitral Days Heart Surgery Symposium" in Stuttgart, Germany

A live presentation of the Minimally-Invasive adjustment capability of the enCorsq

IRVINE, Calif.--(BUSINESS WIRE)--MiCardia Corporation, a privately held medical device company, announced today that a scientific presentation and live surgery of the **en***Cor*<sub>SQ</sub> **Mitral Valve Repair System** were presented at the 2<sup>nd</sup> Mitral Days Heart Surgery Symposium in Stuttgart, Germany to 200 cardiac surgeons and professionals.

Dr Martin Andreas from the Department of Cardiac Surgery at the Medical University of Vienna presented a paper on "The Benefit of Adjustable Annuloplasty Rings" and further described the University's experience with the **enCor**<sub>SQ</sub>. The University of Vienna, under the leadership of Professor Dr Gunther Laufer and Professor Dr Alfred Kocher has one of the leading European experiences with the implantation and adjustment of the **enCor**<sub>SQ</sub>.

"The enCorSQ provides a unique advantage over other annuloplasty rings.

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Dr Markus Czesla from the Department of Cardiac Surgery at the SANA Heart Center in Stuttgart performed a live surgical implant of the **en**  $Cor_{SQ}$  utilizing a minimally invasive right thoracotomy, which was transmitted to the audience in 3D. In addition, Dr Czesla performed a live adjustment of the **en**  $Cor_{SQ}$ . The 65 year patient had experienced a recurrence of regurgitation after 6 months post implant. It should be noted that 15-30% of mitral repair patients have recurrent regurgitation within the first year. Once the device was adjusted, the patient's moderate (MR 2 – 3) regurgitation was reduced to mild (MR1) in less than one (1) minute. The Stuttgart SANA Heart Center, under the leadership of Professor Dr Nicolas Doll has one of the most extensive experiences with the implantation and adjustment of the **en**  $Cor_{SQ}$ .

The **en***Cor*<sub>SQ</sub> device is surgically implanted to treat Mitral Regurgitation (MR) and enables the physician to adjust the device without another surgery to correct any recurrent mitral valve regurgitation that may occur due to the progressive nature of the underlying cardiovascular disease. The adjustment can be achieved, weeks to months post implantation without the need for a repeat high risk surgical procedure. In the European Union, approximately 20,000 mitral valve repair procedures are performed annually. Up to 30% of those patients will experience recurrence of mitral valve regurgitation. To the Company's knowledge, the **en***Cor*<sub>SQ</sub> **Mitral Valve Repair System** is the only device available that can correct recurrent regurgitation without further surgical procedures.

"The **en** $Cor_{SQ}$  provides a unique advantage over other annuloplasty rings. Until now, recurrent mitral regurgitation could only be treated medically or with re-do surgery. With the MiCardia device, recurrent regurgitation can be reduced or eliminated, minimally invasively, without complex redo surgery. This device offers a patient management solution that has otherwise not been available," says Professor Dr Alfred Kocher of the University of Vienna, on his **en** $Cor_{SQ}$  experiences.

## **About Mitral Regurgitation**

Mitral Regurgitation (MR), **mitral insufficiency** or **mitral incompetence**, the most common type of heart valve disorder, occurs when the heart's mitral valve does not close properly resulting in an inadequate blood flow to the body. It is the abnormal leaking of blood from the left ventricle, through the mitral valve, and back into the left atrium when the left ventricle contracts.

Both the American Heart Association (AHA) and the American College of Cardiology (ACC) recommend open-heart surgery to repair or replace the mitral valve for patients who suffer from moderate (Grade 3+) to severe (Grade 4+) mitral regurgitation. Both the AHA and ACC guidelines recommend repair as the operation of choice. An estimated four million people in the United States have significant (>2+) MR, with an annual incidence of 300,000 newly diagnosed patients. Similar incidence of MR exists within the European Union.

"Experience to date with the Company's enCor products has been very promising. The **enCor\_{SQ} Mitral Valve Repair System** functions as a premium mitral repair device but has the unique capability to be adjusted with the Company's proprietary MC-100 RF generator, to increase coaptation of the leaflets and address recurrent mitral regurgitation. Currently, to effectively treat recurrent regurgitation, a repeat open-heart surgery with a heart/lung bypass procedure is required. This promising new approach with the **enCor\_{SQ}** provides a lower risk and more cost effective therapy for these patients," says Don Rohrbaugh, the Company's Chief Executive Officer.

## en Cor<sub>SQ</sub> and Non-Surgical Mitral Adjustment

The MiCardia  $enCor_{SQ}$  Mitral Valve Repair System is a mitral repair device with a permanently attached lead and a proprietary energy source, the MC-100 RF generator. The  $enCor_{SQ}$  is constructed using a memory shape alloy core that has been designed to change its shape when its temperature is elevated a few degrees above body temperature. The device is implanted on the mitral annulus and the permanent lead is tunneled through the atrial wall and implanted under the skin in the chest or abdominal cavity.

If mitral regurgitation recurs, days to months after the initial procedure, the permanent lead is exposed in a minimally invasive manner, using a surgical cut-down. The lead is then connected to the **enCor**<sub>SQ</sub> energy source. The shape of the device is changed, thereby reducing the anterior posterior distance of the mitral valve and eliminating or minimizing the recurrent regurgitation.

#### About MiCardia and en Corso

MiCardia is a privately held medical device company in Irvine CA. The Company is currently marketing its en*Cor*<sub>SQ</sub> Mitral Valve Repair System<sup>™</sup>, in the European Union. The en*Cor*<sub>SQ</sub> device allows the surgeon to address any recurrent MR or coaptation correction, real-time, off-pump, on a beating heart, days or months after the surgical implant. The en*Cor*<sub>SQ</sub> Mitral Valve Repair System has CE market clearance and has been available for clinical use in the EU since January, 2012.

For further information about MiCardia and **en**Cor<sub>SQ</sub>, please visit www.micardia.com.

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