

Infections and d-LVAD

Prof. Antonio Loforte, MD, PhD

University of Turin, Department of Surgical Sciences,
City of Health and Science Hospital Turin,
Cardiac Surgery University Unit,
Turin, ITA



No Disclosures

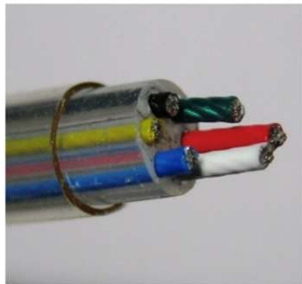
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Energy Transfer - Cable rotary blood pumps with

passive bearings

HeartWare
HVAD



Thoratec
HeartMate-II



Micromed
HeartAssist5



active bearings

Terumo
DuraHeart



BerlinHeart
INCOR



passive magnetic / hydrodynamic ... mechanical

electromagnetic

Complexity

- Motor Leads and Wires
- Flow Sensors
- Cover Shields

Durability and Flexibility (???)

TETS COILS

INFLOW
CANNULA

LIONHEART

OUTFLOWVA
LVE

INFLOW
VALVE

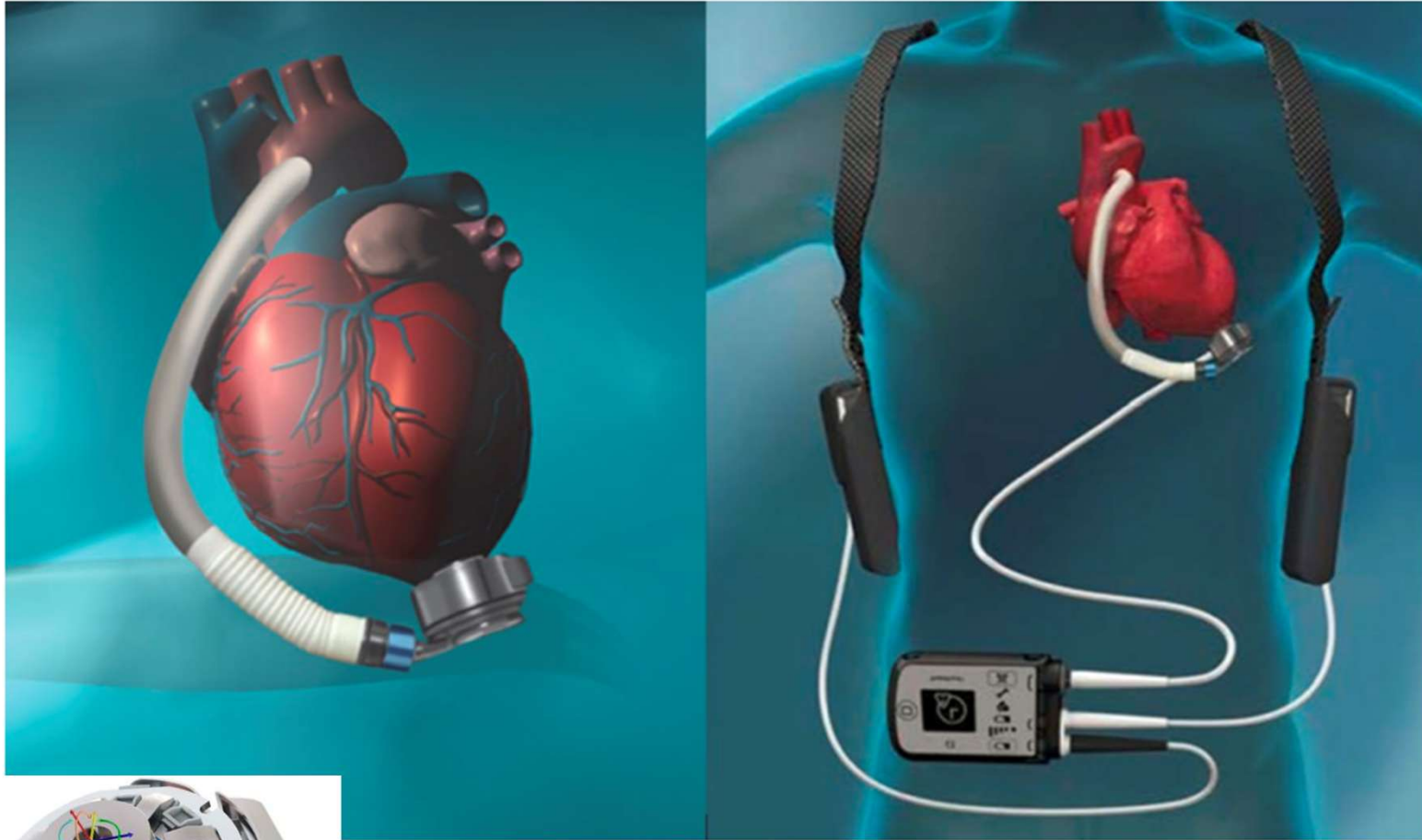
CONNECTORS

CONTROLLER
AND BATTERIES

BLOOD PUMP

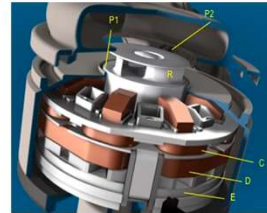
TELEMETRY



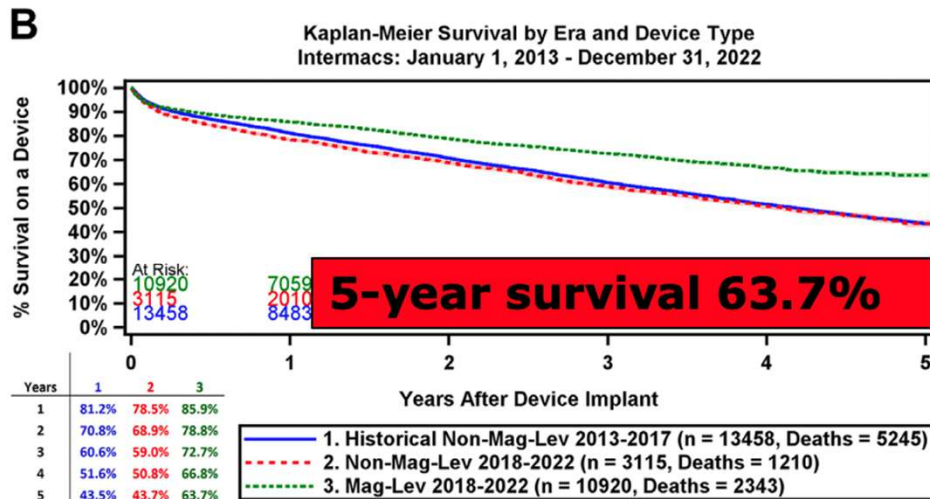


HM3 LVAD – Mid-term outcomes (2)

Real-life - INTERMACS



HM3 vs. older devices



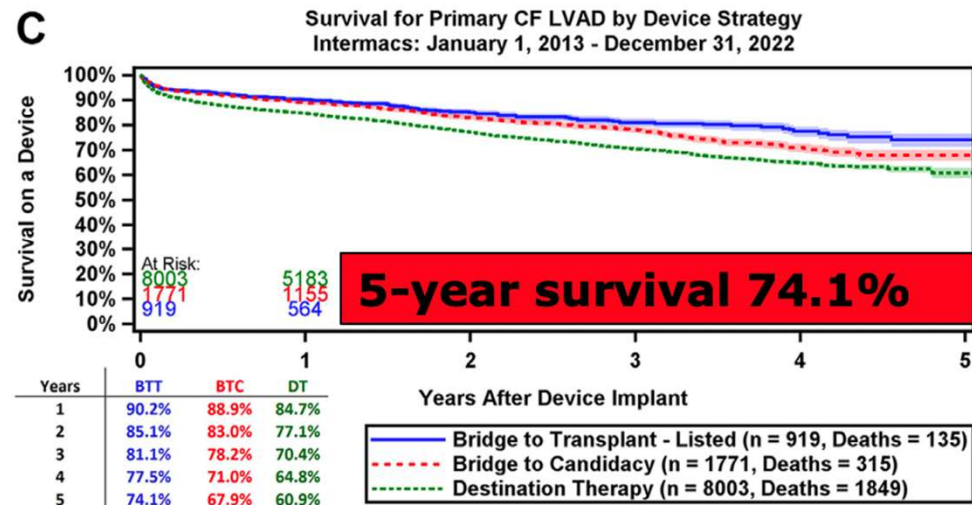
Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

Event: Death (censored at transplant or cessation of support)

72.6% 5-year survival on
HM3 support for pts <50 yrs

Bridge to transplant HM3



Shaded areas indicate 70% confidence limits

p (log-rank) = <.0001

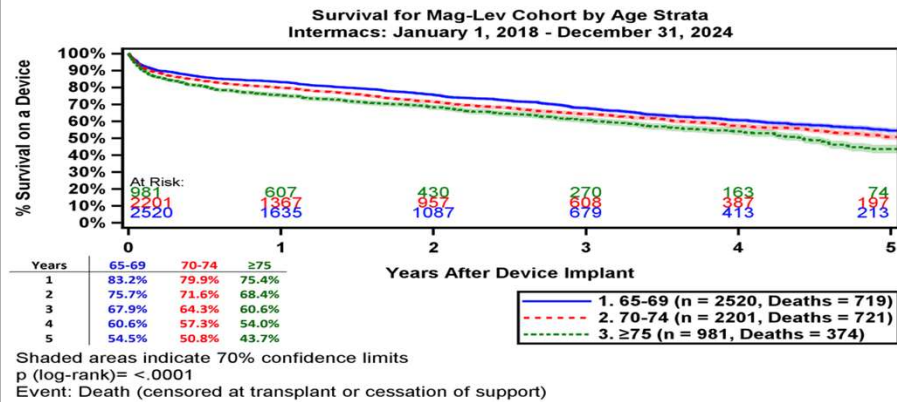
Event: Death (censored at transplant or cessation of support)

Even better mid-term outcomes (similar to HT) among
patients that would have been eligible for transplant

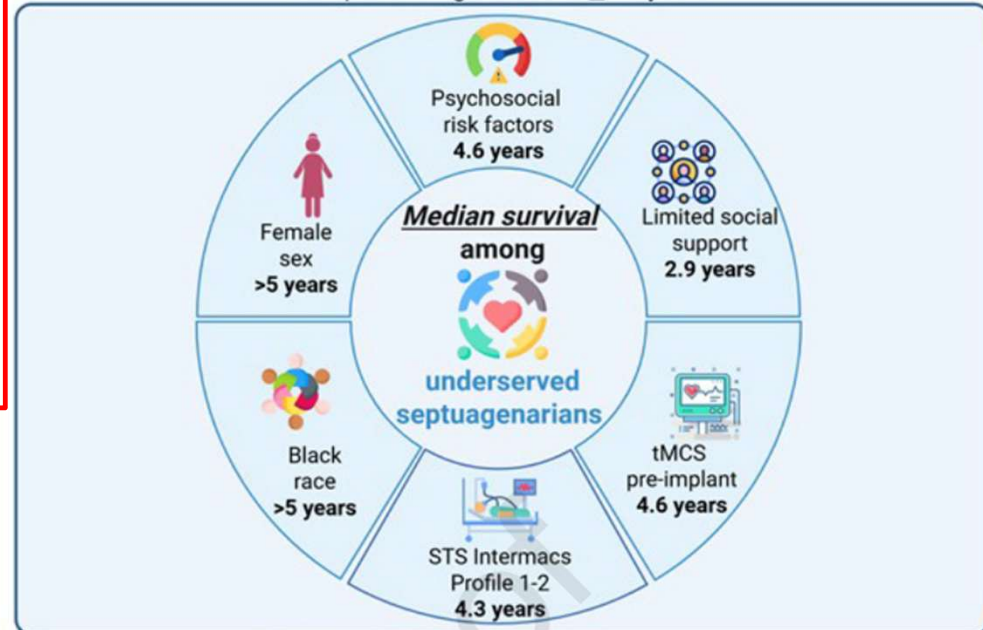
Mehra et al, JAMA. 2022;328(12):1233-1242.

THE STS INTERMACS 2025 ANNUAL REPORT: FOCUS ON OUTCOMES IN OLDER ADULTS

Outcomes in older adults (≥ 65 years) with the Mag-Lev device



Time to broaden patient eligibility?
Reassuring outcomes in historically underserved and/or high risk populations of transplant ineligible adults ≥ 70 years



Meanful improvements in patient reported HRQOL at 6 months

- NYHA class I-II in >50%
- +27 points on KCCQ
- +22 points on EQ-VAS

Excellent survival free from adverse events at 1 year



93.6% Freedom from Stroke



82.9% Freedom from GI Bleeding



89.4% Freedom from Device Infection



97.5% Freedom from Device Malfunction

Nayak, A. (2025) <https://BioRender.com/bxh5uqq>



Areas for further investigation

Individualized approach to heart transplant listing vs. durable LVAD strategy in transplant eligible older adults



Revision of patient eligibility criteria for durable LVAD support, particularly in those ≥70 years



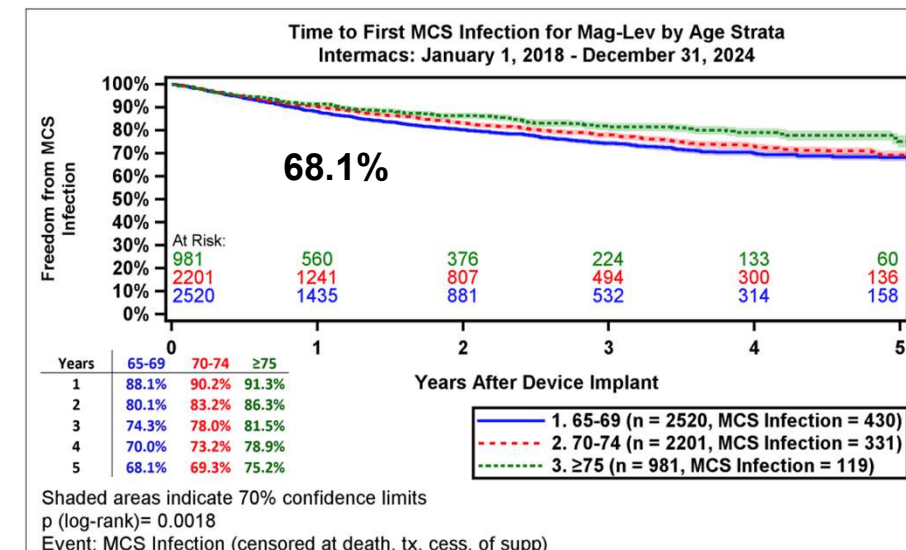
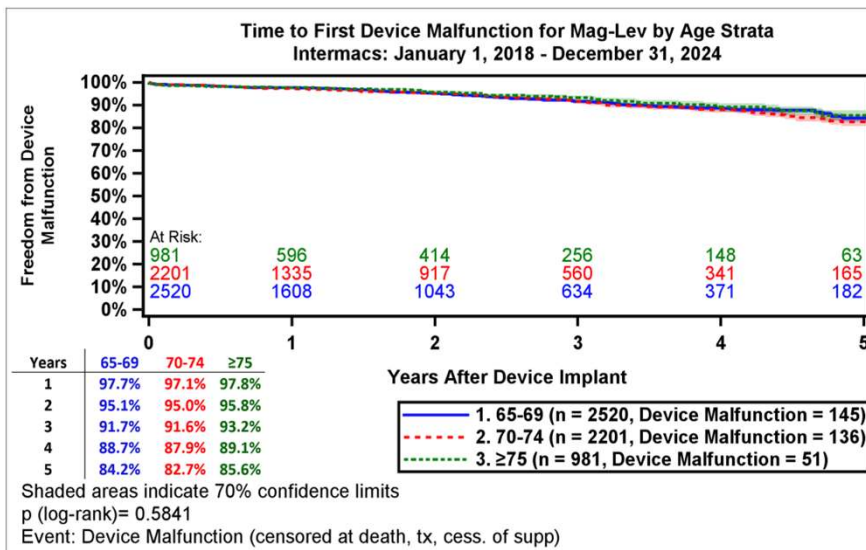
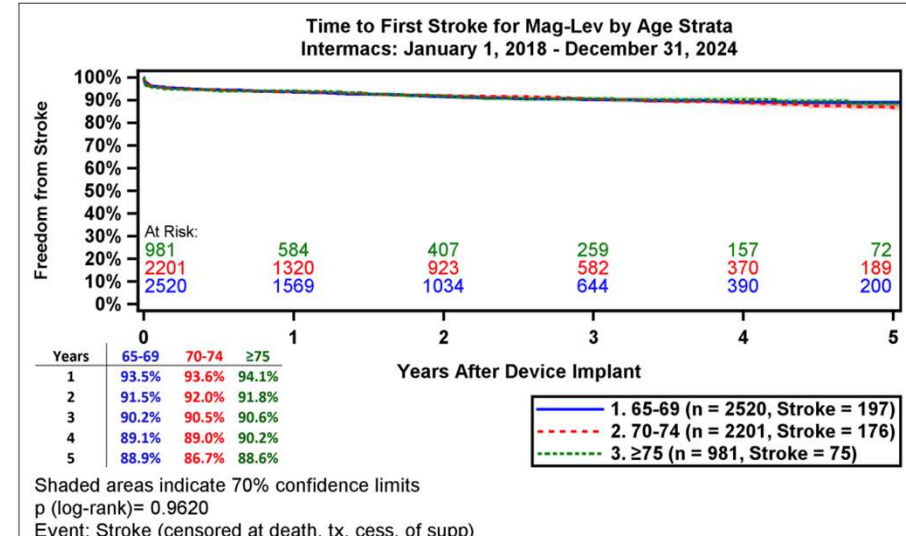
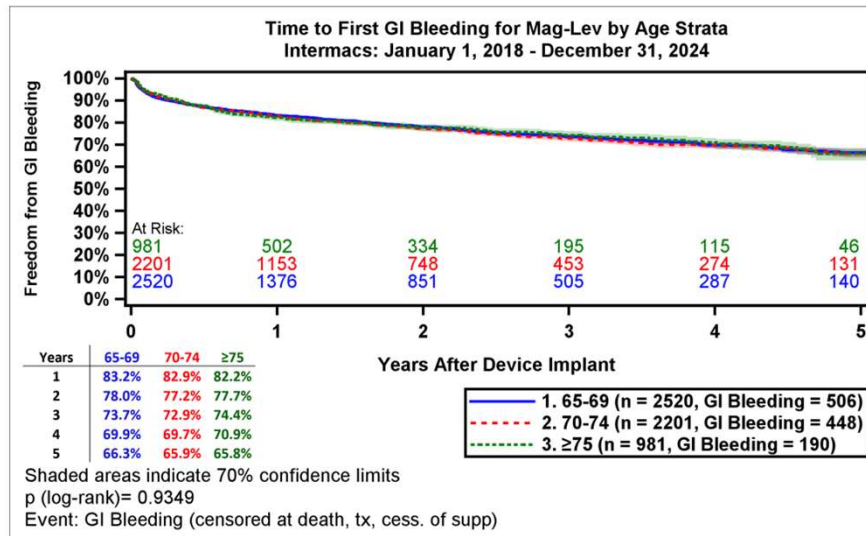
THE ANNALS OF
THORACIC SURGERY

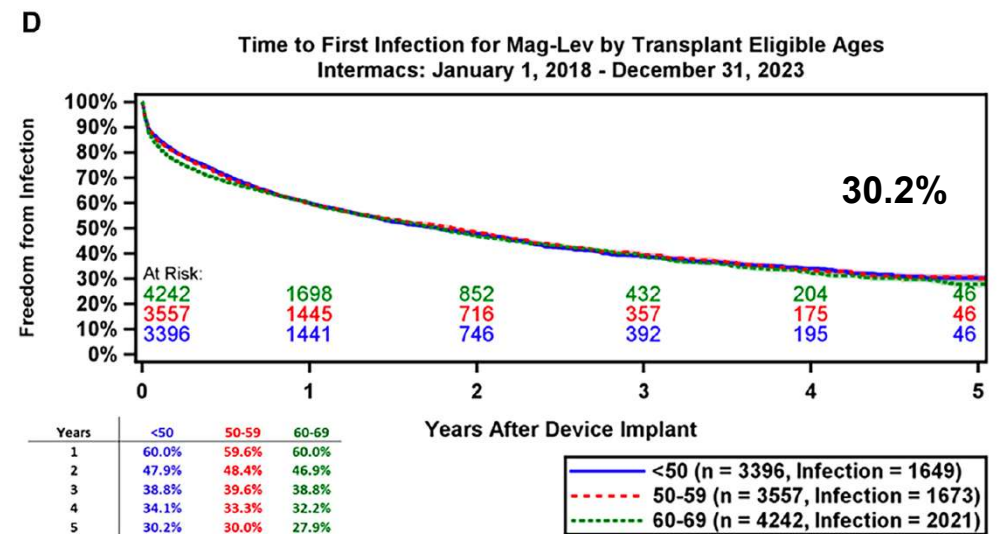
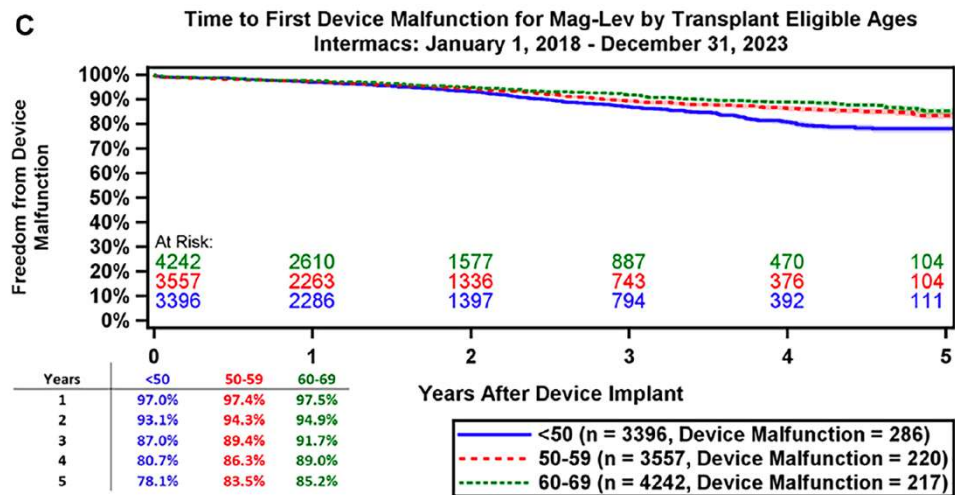
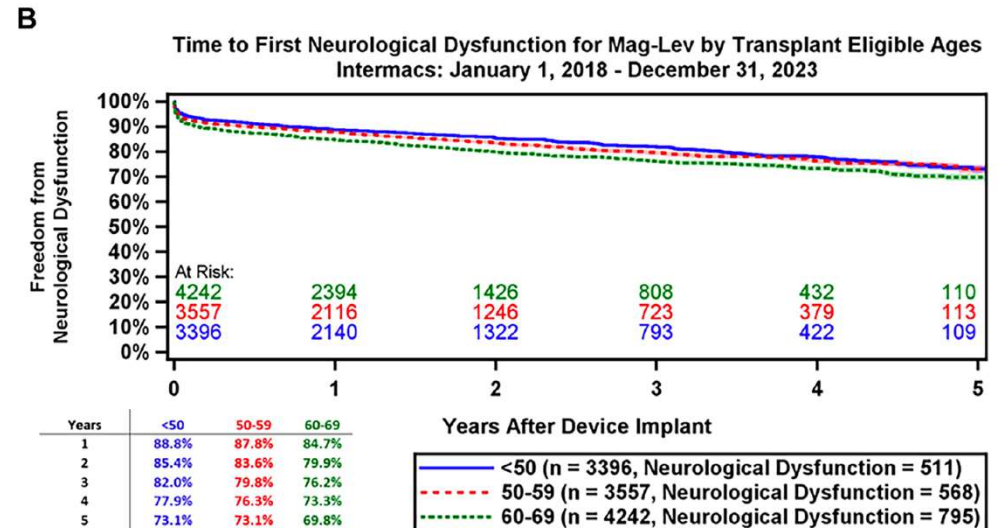
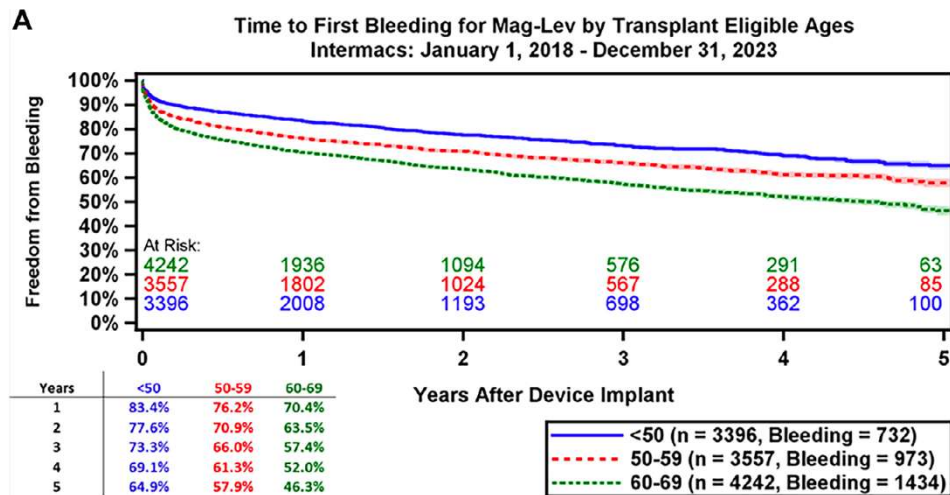
Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

Nayak et al, 2025

@annalsthorsurg #TSSMN

#VisualAbstract #AnnalsImages





2019 EACTS Expert Consensus on long-term mechanical circulatory support

European Journal of Cardio-Thoracic Surgery 56 (2019) 230–270
doi:10.1093/ejcts/ezz098 Advance Access publication 17 May 2019

Evgenij V. Potapov^{a,*†} (EACTS Chairperson), Christiaan Antonides^{b,†},

Maria G. Crespo-Leiro^c, Alain Combes^{d,e}, Gloria Färber^f, Margaret M. Hannan^g, Marian Kukucka^h, Nicolaas de Jongeⁱ, Antonio Loforte^j, Lars H. Lund^k, Paul Mohacsi^l, Michiel Morshuis^m, Ivan Netukaⁿ,

Mustafa Özbaran^o, Federico Pappalardo^p, Anna Mara Scandroglio^q,

Martin Schweiger^r, Steven Tsui^s, Daniel Zimpfer^t and Finn Gustafsson^{u,*} (EACTS Chairperson),

The Task Force on Long-Term Mechanical Circulatory Support of the EACTS

Preventing infection postimplant			
It is recommended that the velour part of the driveline not exit the body.	I	C	[259]
Stabilization of the driveline immediately after the device is implanted and continuing throughout the duration of support is recommended.	I	C	[491]
A dressing change protocol initiated immediately postoperatively is recommended.	I	B	[491, 492]
Secondary antibiotic prophylaxis for the prevention of infectious events during routine procedures and dental work due to the risk of bacteraemia should be considered.	Ila	C	[71, 493, 494]

1**Appearance:**

- little or no redness
- no drainage
- skin is incorporated (stuck) to the driveline
- no tenderness

2**Appearance:**

- initial tear or trauma to exit site (ex. dropped controller), skin pulled away from driveline
- slight tenderness
- drainage - note amount, color, odor
- slight redness

Page an MCS Nurse immediately, take pictures if possible

3**Appearance:**

- redness increasing
- drainage increasing- note amount, color, odor
- tenderness
- skin pulled away from driveline

4**Appearance:**

- large amount of redness
- large amount of drainage
- painful
- skin is pulled away from the driveline

Exit Site Scale



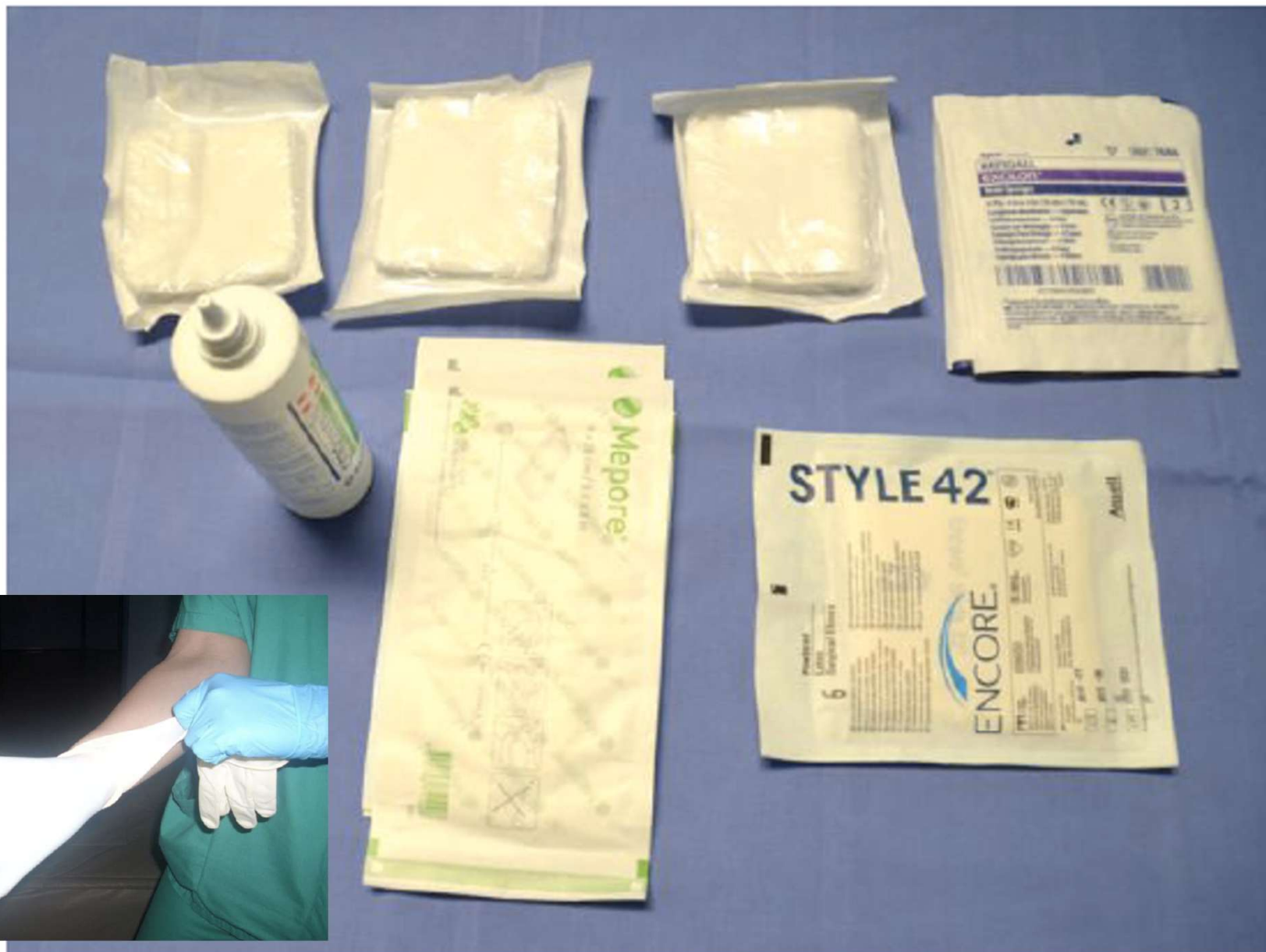
**Utah Artificial
Heart Program**
INTERMOUNTAIN
HEALTHCARE

Driveline exit-site care protocols in patients with left ventricular assist devices: a systematic review

Zeliha Ozdemir Koken^{1b}, Yunus C. Yalcin^{2,3c}, Diana van Netten⁴, Chantal C. de Bakker⁵,
Maaike van der Graaf⁶, Umit Kervan⁷, Nellanne J. Verkaik⁸ and Kadir Caliskan^{9,10}

STANDARDIZZAZIONE E PROTOCOLLI SONO ALLA BASE DELLA PREVENZIONE DELLE INFEZIONI DELLA DRIVELINE





Guanti sterili



**Exit site of pump lead
without problems**



**Extensive disinfection with
Softasept or Octenisept**



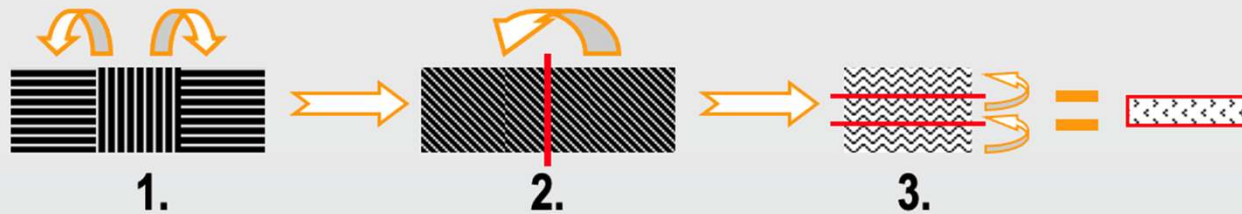
**Compress soaked in disinfection is
placed under lead**



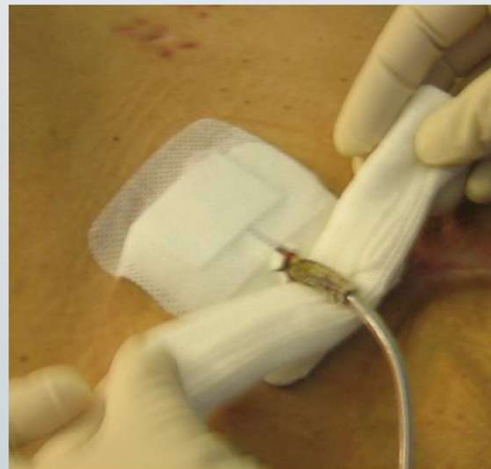
**Pre-cut metallic-coated compress (silver side next
to the skin) is placed around the lead**



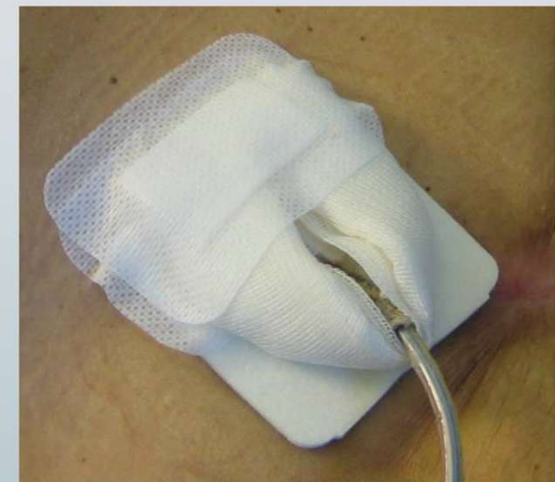
**Compress is fixed with a sterile
plaster**



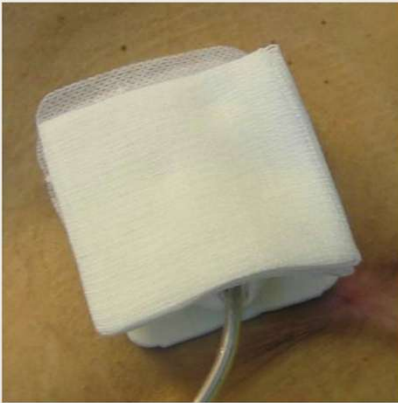
1. Unfold a small compress (7.5x7.5 cm)
2. fold in the middle
3. fold twice to 1/3



4. Place the folded compress around the lead, without bending the lead upwards



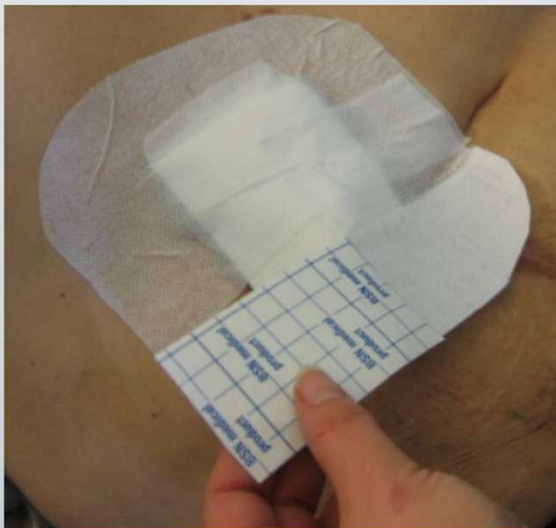
5. Fix with a sterile plaster



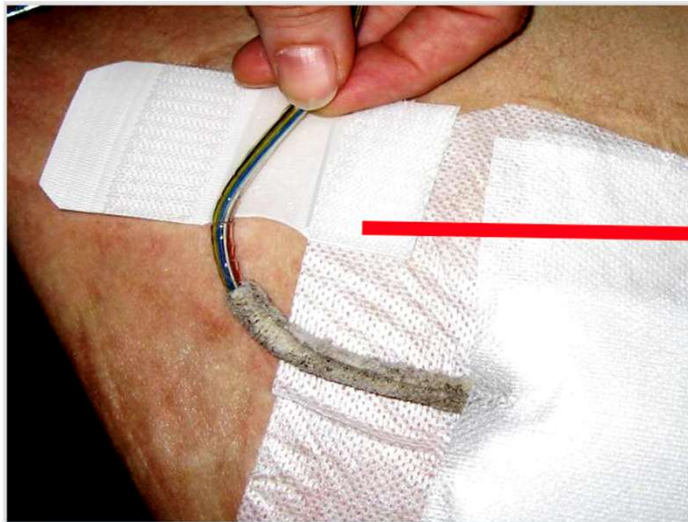
Cover with a compress



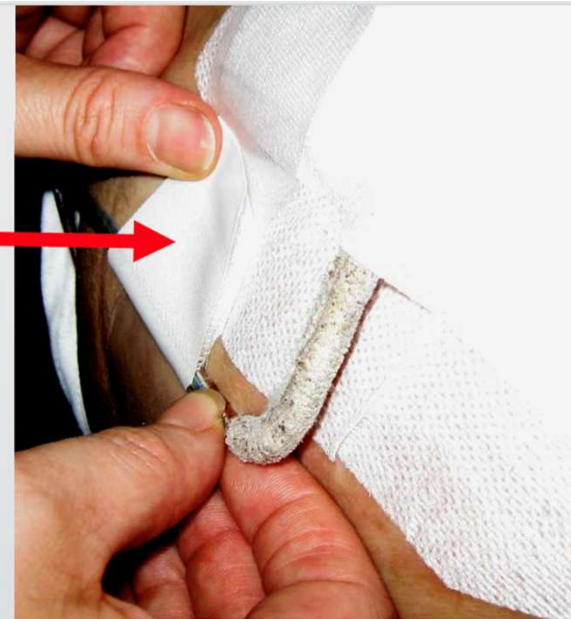
Fix the upper half with a large plaster



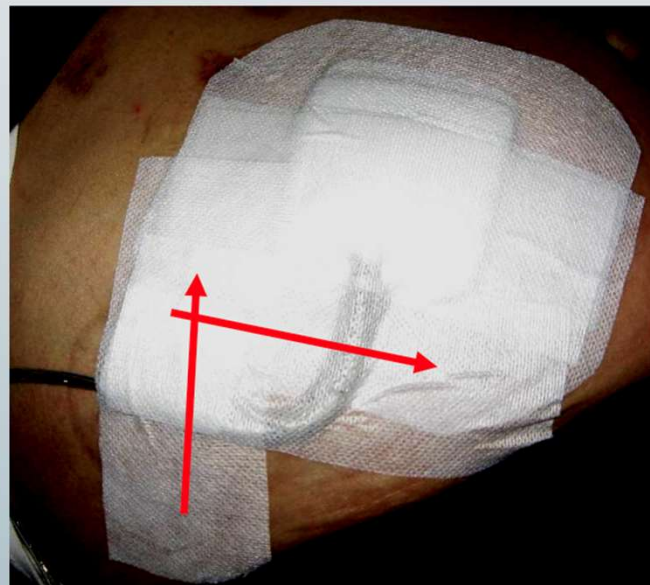
....and the lower half with a slit plaster from bottom to top



Fixationsplaster so positionieren, dass das Kabel
eine geschwungene Linie bildet, nicht ein

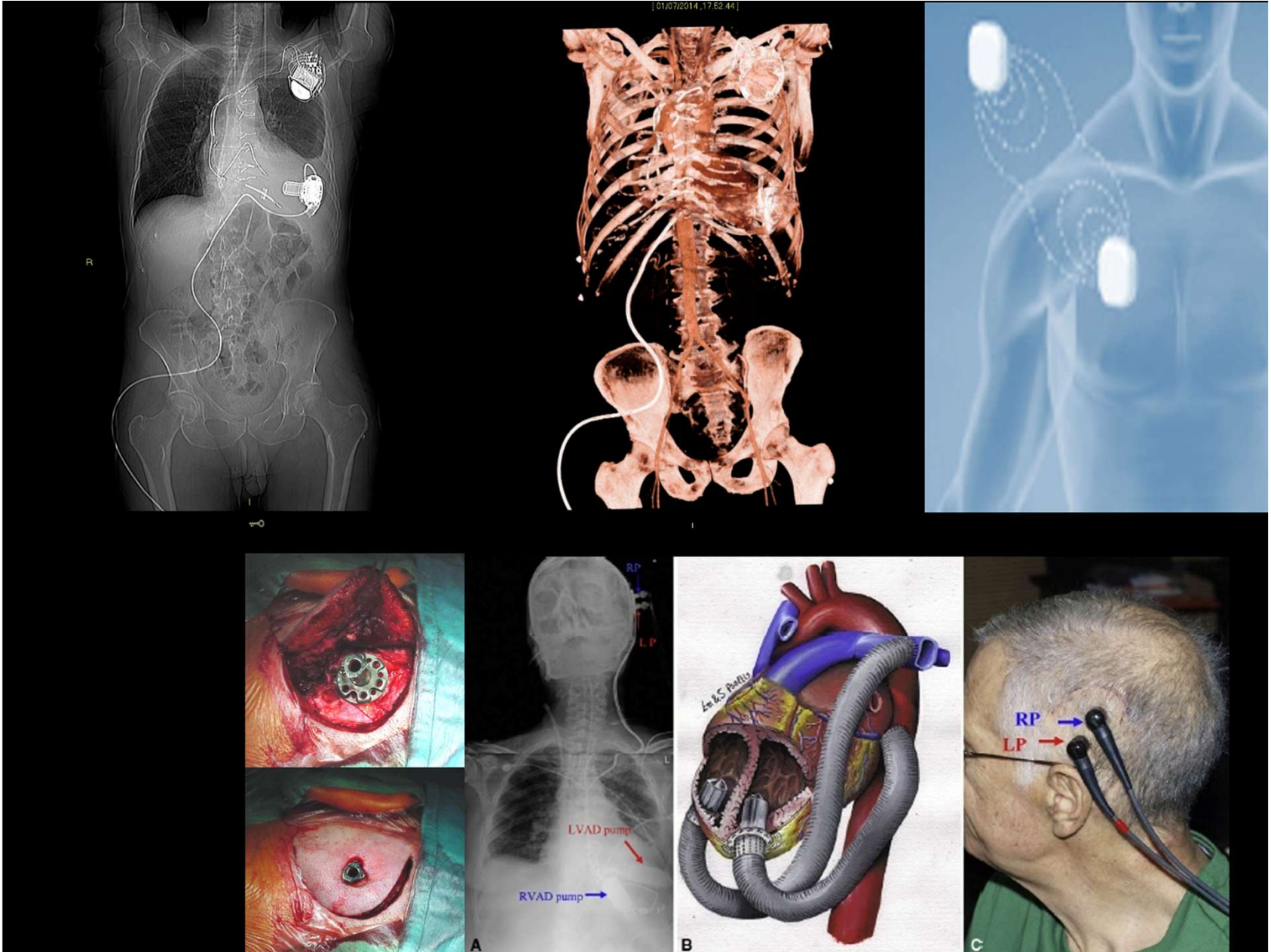


**Stabilize additionally with
fixation plaster**



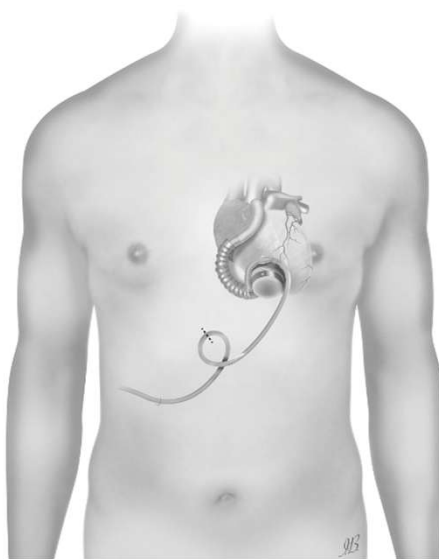
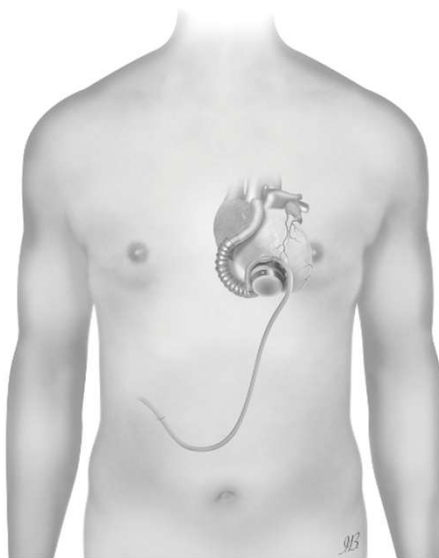
**A further fixation
plaster is stuck
perpendicularly
to the lead**

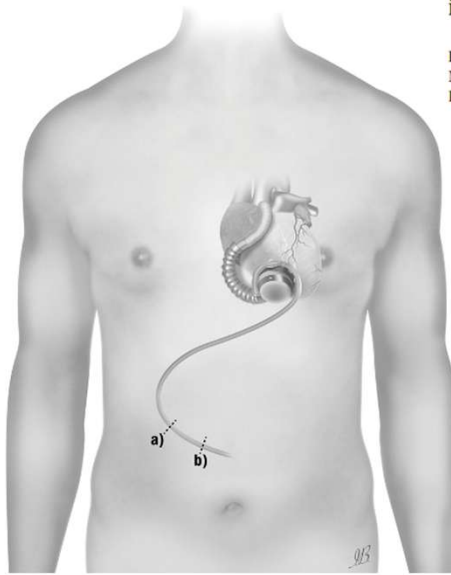




Modified HeartMate II Driveline Externalization Technique Significantly Decreases Incidence of Infection and Improves Long-Term Survival

AJEET SINGH,* MARK J. RUSSO,* TRACY B. VALEROSO,* ALLEN S. ANDERSON,† JONATHAN D. RICH,†
VALLUVAN JEEVANANDAM,* AND SHAHAB A. AKHTER‡

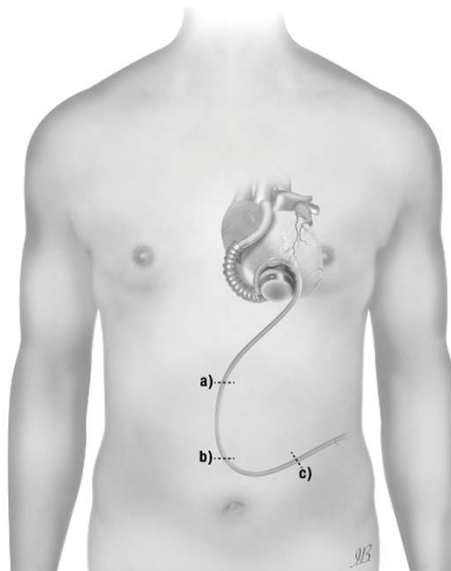




Double tunnel technique for the LVAD driveline: improved management regarding driveline infections

David Schibilsky · Christoph Benk · Christoph Haller ·
Michael Berchtold-Herz · Matthias Siepe ·
Friedhelm Beyersdorf · Christian Schlensak

J Artif Organs (2012) 15:44–48



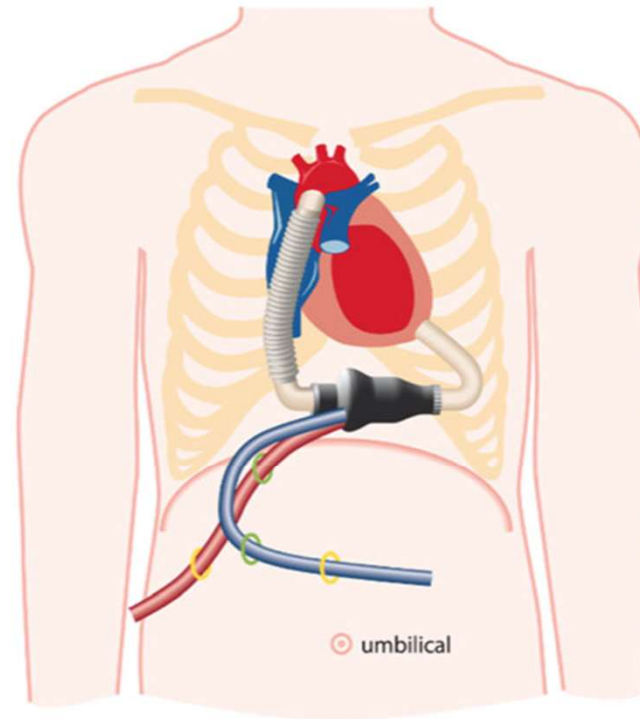
Reduction of Driveline Infections Through Doubled Driveline Tunneling of Left Ventricular Assist Devices

*†Felix Fleissner, *Murat Avsar, *Doris Malehsa,
*Martin Strueber, *Axel Haverich,
and *Jan D. Schmitto

*Division of Cardiac, Thoracic, Transplantation and
Vascular Surgery, Hannover Medical School; and

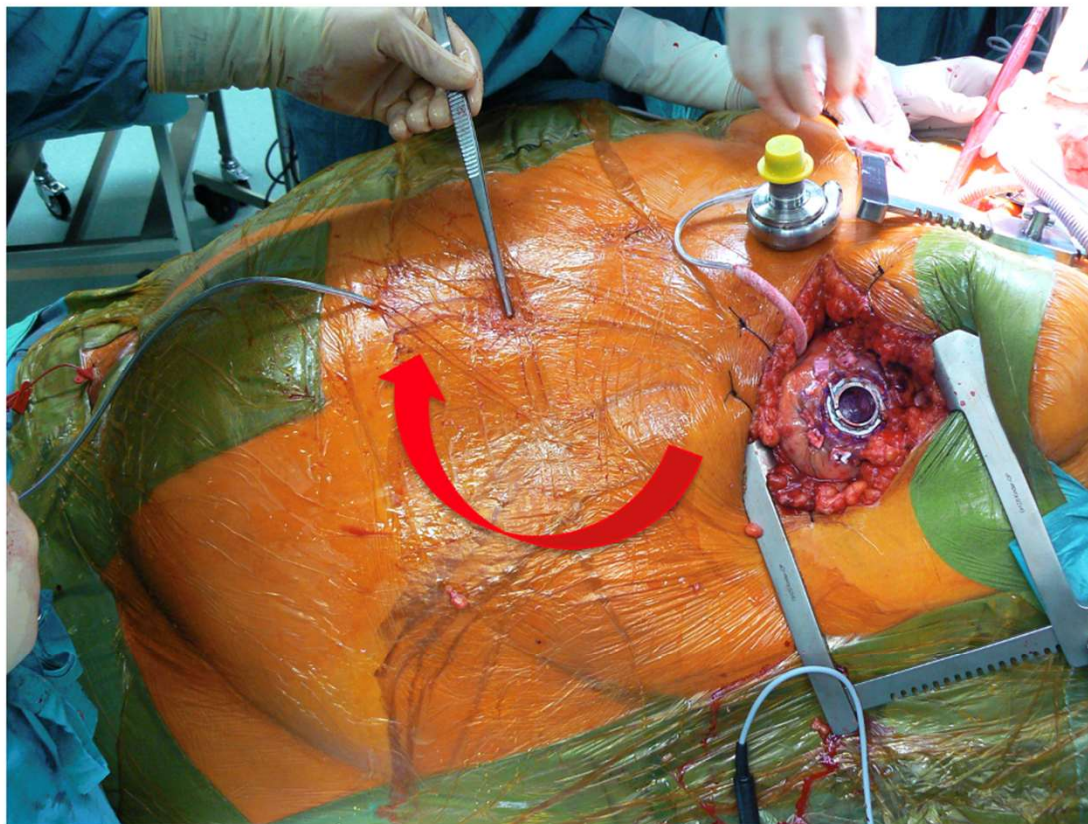
†Institute for Molecular and Translational
Therapeutic Strategies (IMTTS), Hannover Medical
School, Hannover, Germany

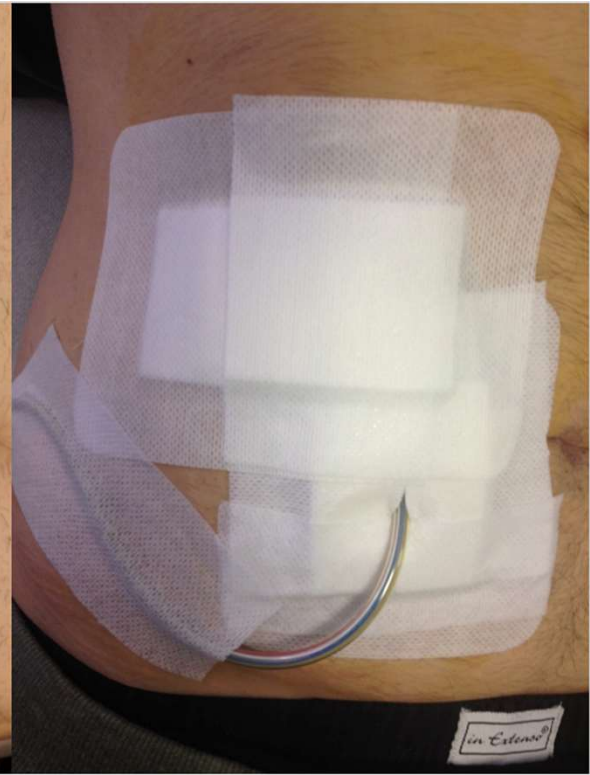
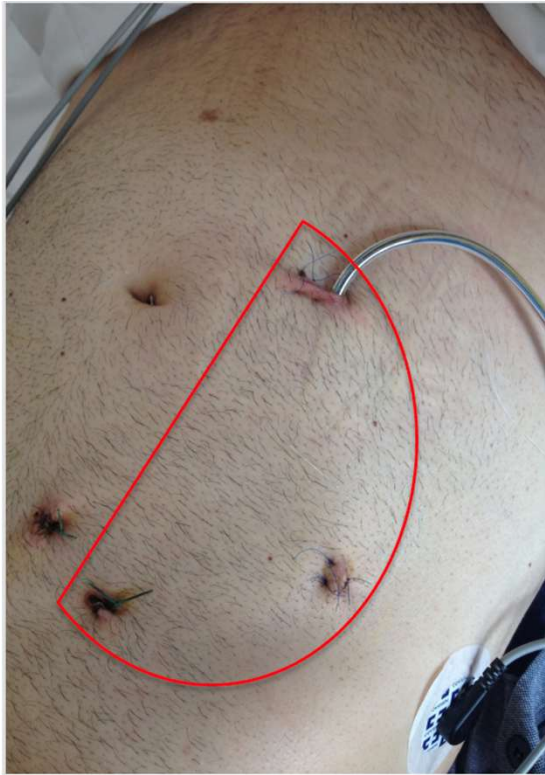
Artif Organs, Vol. 37, No. 1, 2013



○ fascial transition

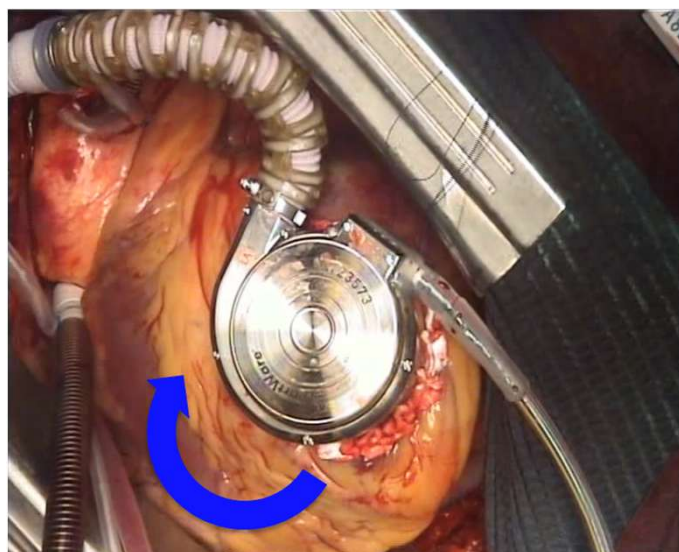
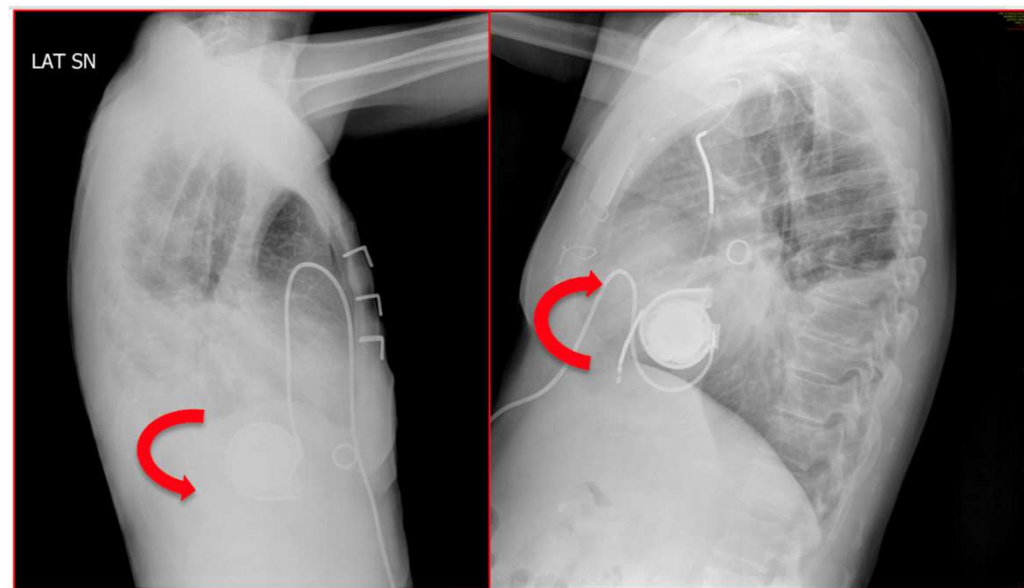
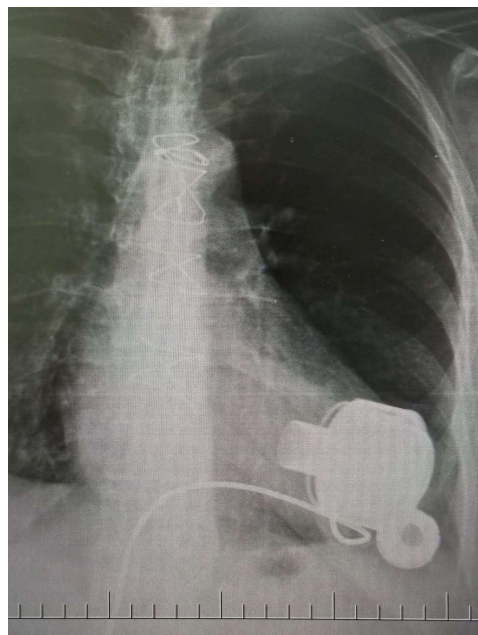
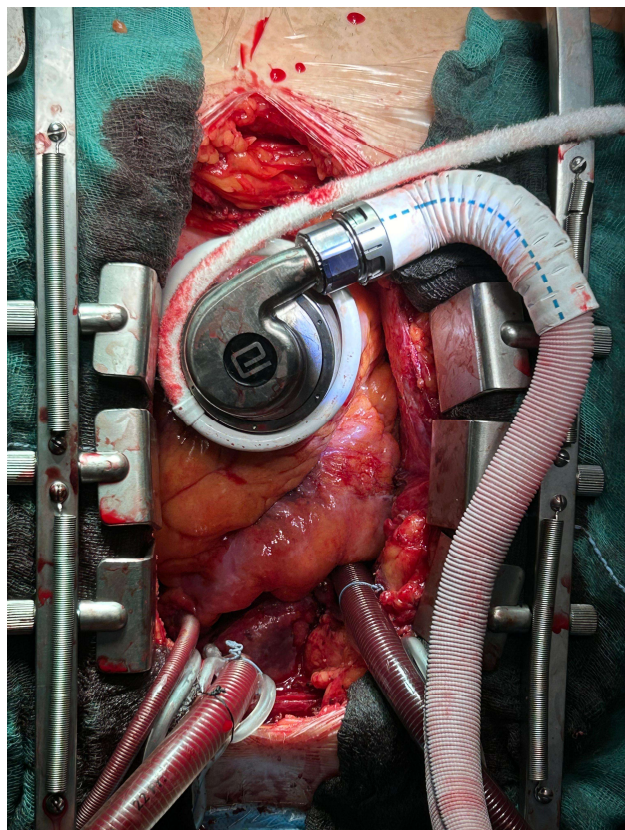
○ skin exit site





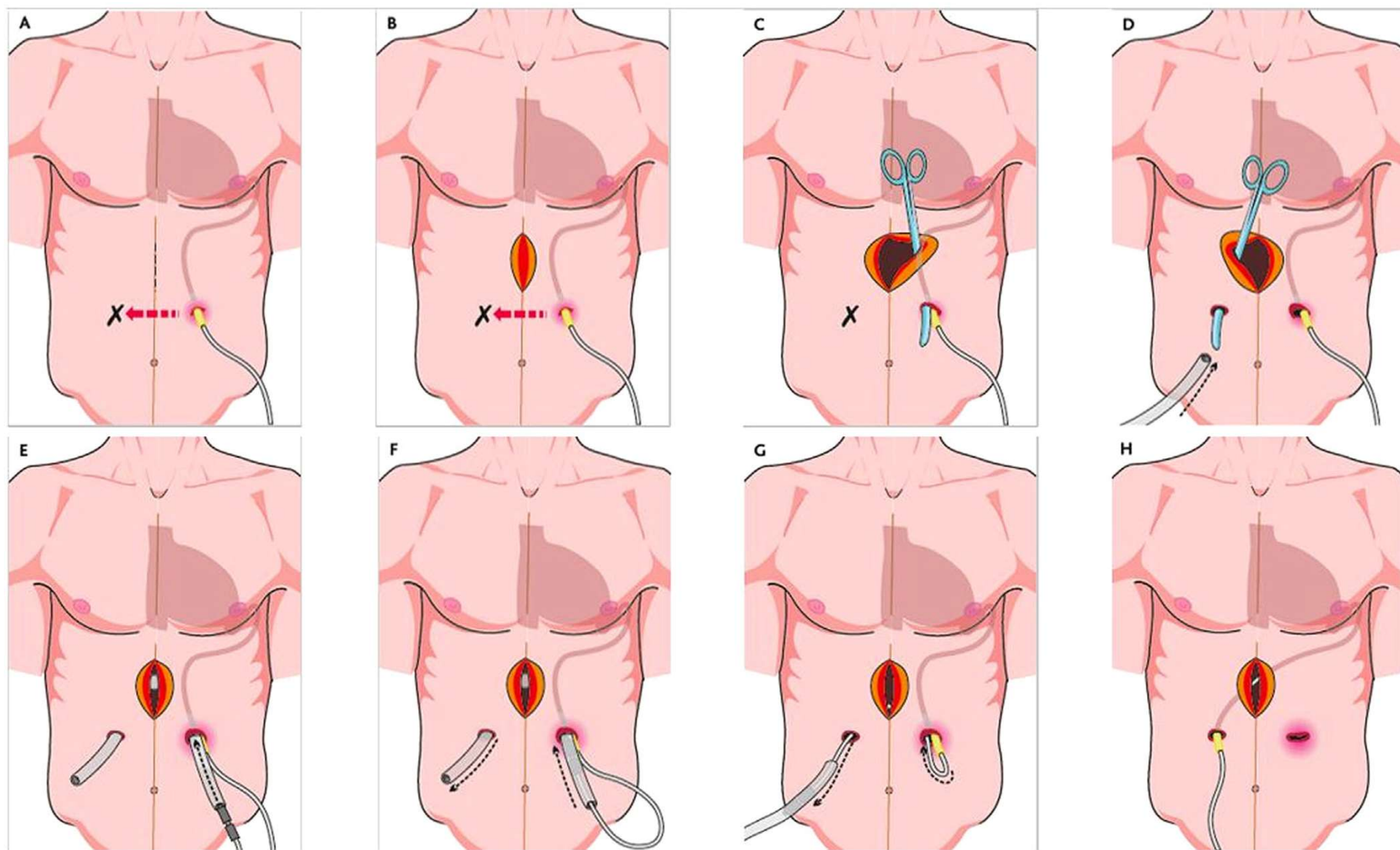
... Vs.





Single positron emission tomography/computed tomography combined with radiolabelled leucocytes for the detection of location of infection and infected emboli should be considered.	IIa	C
Leucocyte radiolabelled scintigraphy for identification of deep infection may be considered.	IIb	C
If the infection is not eradicated despite debridement and 6 weeks of systemic intravenous antibiotic treatment, specific surgical treatment of the infections should be considered, including driveline relocation, pump exchange, prolonged treatment of the ventricular assist device, wrapping driveline with omentum and a heart transplant.	IIa	C
Lifelong antibiotic treatment for complicated <i>S. aureus</i> infection should be considered unless there is an option to remove the device.	IIa	C

6 weeks rule !

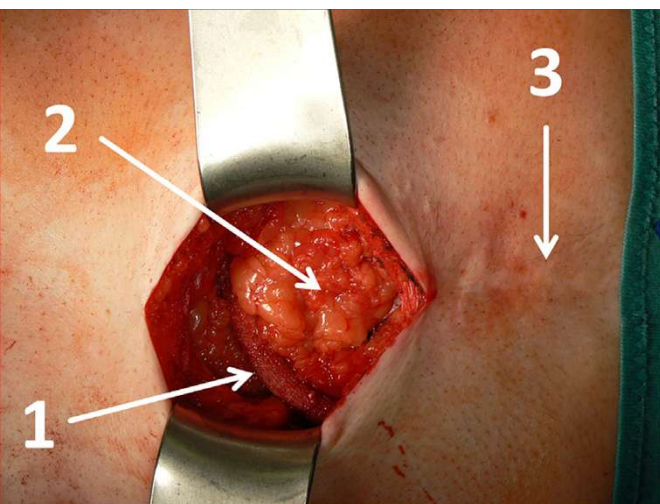












- ▶ **Intraabdominal device implantation leads to reduced risk of infection**

Wasler et al. ASAIO Journal 1996; 42: M573-M576

- ▶ **Intraabdominal prosthetic device pocket leads to reduced risk of infection and reduces complications**

Holman et al. J Heart Lung Transplant 2008 Mar;27(3):268-71.

Icenogle et al. J Heart Lung Transplant 2003; 22:818-821

Treatment of patients with mechanical circulatory support with a suspected infection of the driveline exit site or the driveline itself		
A full evaluation as outlined above should be performed in all patients prior to treatment before commencing antimicrobial treatment even if only superficial infection is suspected.	I	C
In patients with a superficial driveline exit site infection but without a BSI or systemic illness, it is recommended that antibiotic therapy be deferred until culture results are known.	I	C
In patients with clinical signs of driveline exit site infection but with negative culture results, initiation of empirical oral antibiotic therapy and evaluation based on clinical response are recommended.	I	C
In the presence of systemic illness and/or sepsis, initiation of empirical intravenous antibacterial therapy always covering <i>Staphylococcus</i> , <i>Pseudomonas</i> and <i>Enterobacteriaceae</i> species, also taking local institutional epidemiology and colonization (e.g. methicillin-resistant <i>Staphylococcus aureus</i> , vancomycin-resistant <i>Enterococci</i>) into consideration, is recommended.	I	C
Rifampicin should usually be avoided due to its significant impact on the international normalized ratio, but it may be considered in rare cases.	IIb	C
It is recommended that the duration of antimicrobial treatment be guided by the clinical response, type of infection, pathogen(s), transplant status and the opinion of an infectious disease expert.	I	C
It is recommended that the treatment of a superficial infection without an associated BSI last at least 2 weeks.	I	C
For deep infections, treatment for at least 6 weeks, depending on the pathogen, time to clearance of the BSI, the clinical response and the expert opinion of an infection disease expert, are recommended.	I	C

Treatment of patients with mechanical circulatory support with a suspected infection of the pump		
In all patients with mechanical circulatory support, a full evaluation for any suspected infection as outlined above should be performed before commencing antimicrobial treatment.	I	C
In the case of a persistent bloodstream infection, pump seeding or endovascular infection should be suspected. It is recommended that intravenous antimicrobial therapy be initiated after microbiological samples have been taken.	I	C
For infection in patients with mechanical circulatory support at the time of device exchange or heart transplant, it is recommended that antimicrobial therapy be continued for at least 6 weeks, depending on the pathogen and the clinical course, to minimize the risk of relapse.	I	C
After failure of eradication of infection with debridement and 6 weeks of systemic intravenous antibiotic treatment, specific surgical treatment of infections including pump exchange and a heart transplant should be considered.	IIa	C

6 weeks rule !

Relation of Left Ventricular Assist Device Infections With Cardiac Transplant Outcomes



Aditya Parikh, MD^{a,*}, Michael Halista, MD^b, Samantha Raymond, MPH^c, Jason Feinman, MD^b, Donna Mancini, MD^a, Sumeet Mitter, MD^a, Maya Barghash, MD^a, Maria Trivieri, MD^a, Johanna Contreras, MD^a, Sarah Taimur, MD^a, Julie Roldan, AGACNP^a, Joseph Murphy, RN^a, Amit Pawale, MD^d, Anelechi Anyanwu, MD^d, Noah Moss, MD^a, Anuradha Lala, MD^a, and Sean Pinney, MD^a

(Am J Cardiol 2021;160:67–74)

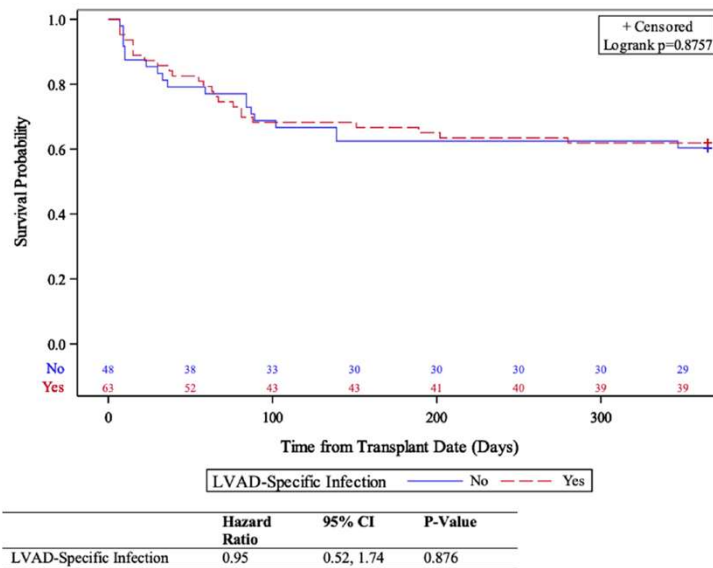


Figure 3. Impact of LSI on long-term outcome of allograft rejection and death within 1 year after HT. CI = confidence interval.

Outcomes of Heart Transplant After Left Ventricular Assist Device Specific and Related Infection

Michael Z. Tong, MD, MBA, Nicholas G. Smedira, MD, Edward G. Soltesz, MD, MPH, Randall C. Starling, MD, MPH, Christine E. Koval, MD, Liane Porepa, MD, and Nader Moazami, MD

Departments of Thoracic and Cardiovascular Surgery, and Cardiovascular Medicine, Heart and Vascular Institute; and Department of Infectious Disease, Medicine Institute, Cleveland Clinic Foundation, Cleveland, Ohio

(Ann Thorac Surg 2015;100:1292–7)

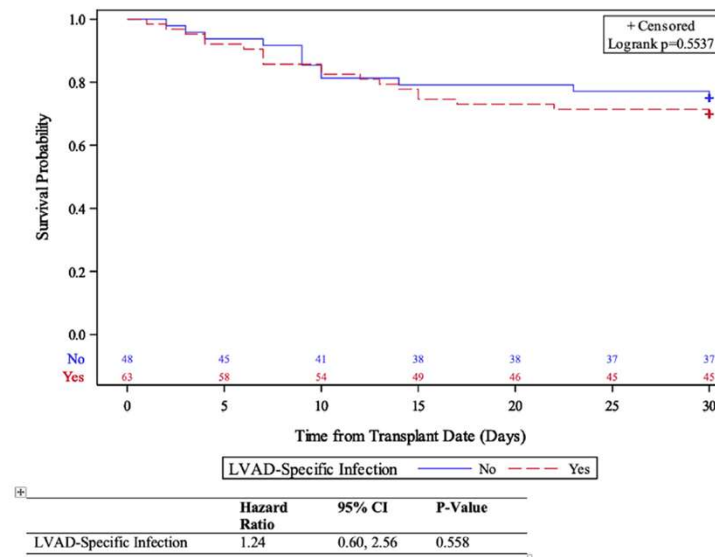


Figure 2. Impact of LSI on short-term outcome of acute renal failure, allograft rejection, and death at 30 days after HT. CI = confidence interval.

Association between continuous-flow left ventricular assist device infections requiring long-term antibiotic use and post-heart transplant morbidity and mortality

Maria Lambadaris MD¹ | Julie K. K. Vishram-Nielsen MD, PhD^{1,2} |
Jennifer M. Amadio MD, MEHP^{1,3} | Shahid Husain MD, PhD¹ |
Vivek Rao MD, PhD^{1,3} | Filio Billia MD, PhD^{1,4} | Ana C. Alba MD, PhD^{1,4}

J Card Surg. 2022;37:96–104.

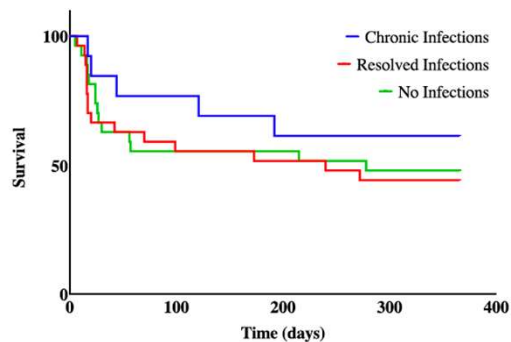


FIGURE 6 Kaplan-Meier curve of rejection within 1-year post-discharge from a heart transplant in patients with (1) LVAD-specific infection on chronic suppressive antibiotics (blue); (2) resolved LVAD infection (red); and (3) no LVAD infection (green). Logrank $p = .5$. LVAD, left ventricular assist device

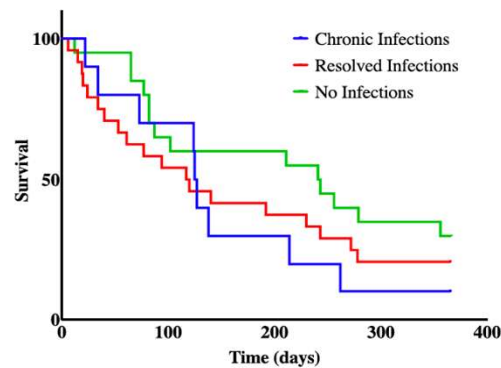


FIGURE 5 Kaplan-Meier curve of infection at 1-year post-discharge from a heart transplant in patients with (1) LVAD-specific infection on chronic suppressive antibiotics (blue); (2) resolved LVAD infection (red); and (3) no LVAD infection (green). Logrank $p = .3$. LVAD, left ventricular assist device

	Absolute risk	HR (95% CI)	<i>p</i>
Chronic infection versus no infection			
Infection	92% versus 78%	1.2 (0.6–2.5)	.6
Rejection	38% versus 59%	0.5 (0.2–1.5)	.2
Death	8% versus 15%	0.4 (0.1–3.9)	.5
Resolved infection versus no infection			
Infection	81% versus 78%	1.4 (0.8–2.6)	.2
Rejection	63% versus 59%	1.3 (0.6–2.5)	.5
Death	15% versus 15%	0.9 (0.2–3.6)	.9

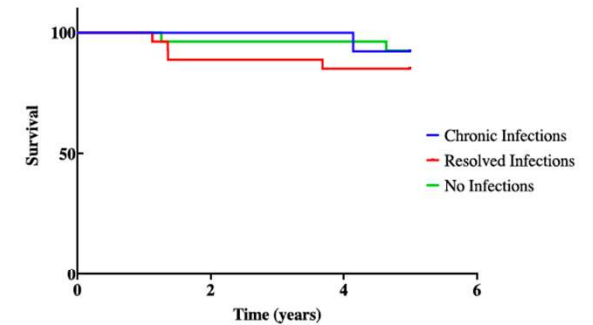


FIGURE 7 Kaplan-Meier curve of mortality up until 5 years post-heart transplant in patients with (1) LVAD-specific infection on chronic suppressive antibiotics (blue); (2) resolved LVAD infection (red); and (3) no LVAD infection (green). Logrank $p = .6$. LVAD, left ventricular assist device

Wireless Heart Pump Technology Implanted in a Patient for the First Time



J Heart Lung Transplant 2019;38:339–343

EXTERNAL COMPONENTS



User Watch - status and alarm generation to the patient; Connects via MICS protocol to both the internal and external controllers and collects the vital statistics from them.



Power Transmission Belt - transmits power to the internal receiver coil via magnetic coupling. The coil is built from Litz wires with state of the art resonance structure technology and can supply up to 30 Watts at high efficiency.



External Controller - runs the power transmission control algorithm, communicates via standard MICS protocol with the implant; pushes power to the belt using special power driver circuits.



External Battery - main power source for generating the electromagnetic field. Similar battery to those used with current LVADs.



Doctor's Tablet - used mainly for patient specific configuration during device initialization;

IMPLANT COMPONENTS

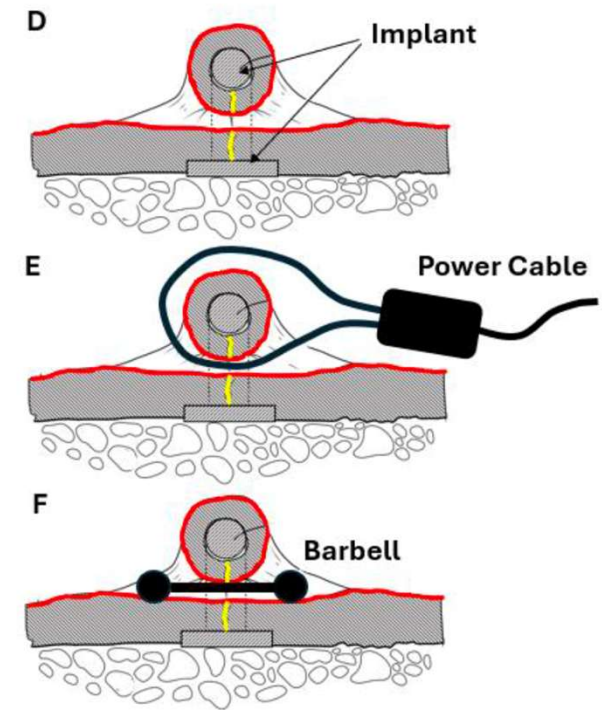
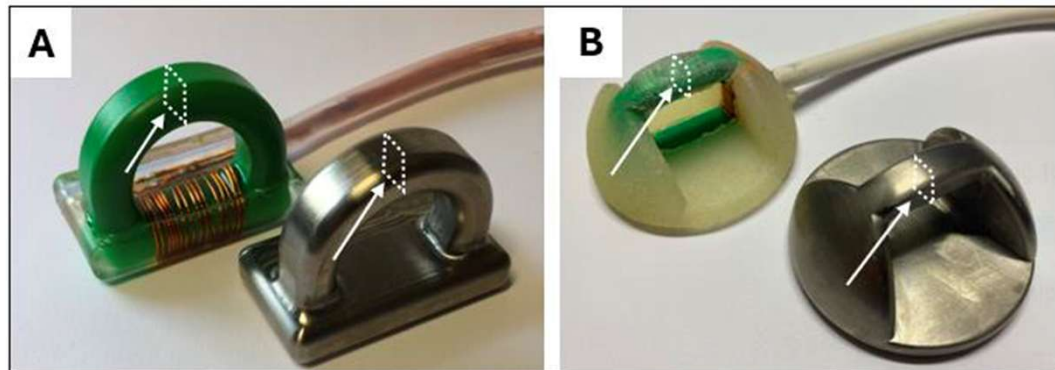
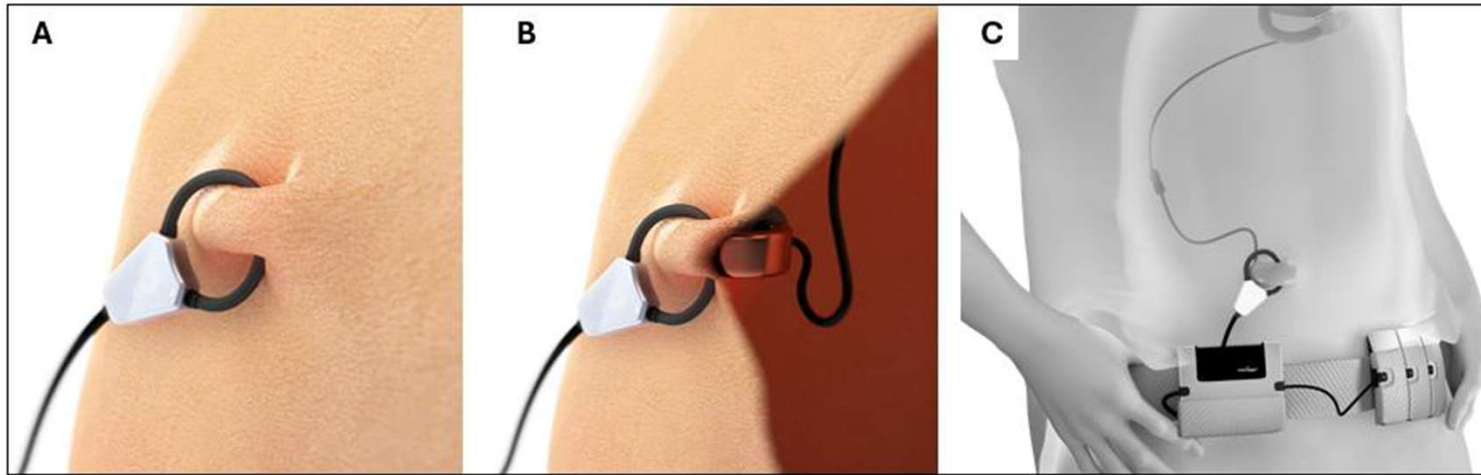


Implant Coil Ring - Receives power from the external Power Transmission Belt. It is placed around the lung and fixated to the chest wall. The coil possesses state of the art resonance structure technology and high power receiving capability.



Internal Controller and Battery - controls the power receiver circuits, activates the VAD brushless DC motor, communicates with the external controller through standard MICS protocol, and controls the battery smart charging circuits. The battery provides power backup and enables several hours of operation without the external Power Transmission Belt.





Mechanical Circulatory Support Workshop



26-27 June 2026
Turin, Italy



With the scientific collaboration of Acute CardioVascular Care (ACVC) and the European Association of Percutaneous Cardiovascular Interventions (EAPCI), of the ESC

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Mechanical Circulatory Support Workshop



Skills Level 2 – Residents in the final years of training and surgeons at the beginning of independent practice.
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A hybrid between a pacemaker and a cardiac assist device, ICOMS FLOWMAKER® is the first definitive therapeutic solution capable of helping the heart restore its natural rhythm.



FineHeart granted first two patents in China for the FLOWMAKER®

Bordeaux, France, April 25, 2022 – FineHeart S.A, a medical device company developing the FLOWMAKER®, a fully implantable cardiac output restoration system (ICOMS) to address the unmet needs of patients suffering from severe heart failure, announced today that its first two patents have been granted in China by the CNIPA – China National Intellectual Property Administration –.

