

LEVERAGING EXPERTISE TO MAKE A SAFER,  
LESS INVASIVE ARTERIALIZATION  
PROCEDURE FOR CHRONIC LIMB  
THREATENING ISCHEMIA (CLTI)



# CHALLENGE

Design, develop and commercialize a minimally invasive device that resolves Chronic Limb Threatening Ischemia (CLTI), a severe blockage in the arteries of the lower extremities that markedly reduces blood flow for patients who have failed standard revascularization approaches and are facing imminent risk of major leg amputation.

# OUTCOME

A revolutionary set of devices that was co-developed, manufactured, and kitted by Heraeus based on customer IP that is:

- > Vertically Integrated
- > Tested and Submitted for Approval
- > Distributed by the Customer
- > Producing Better Patient Outcomes

# SUMMARY

By leveraging internal expertise in catheters, ballooning, and coatings, Heraeus was able to develop, test, submit and scale the product for the customer in under 36 months, including consolidating vendors, supporting two international regulatory submissions and clinical studies conducted by the customer, and improving overall results and quality of life for patients.

## MARKET

Peripheral Vascular

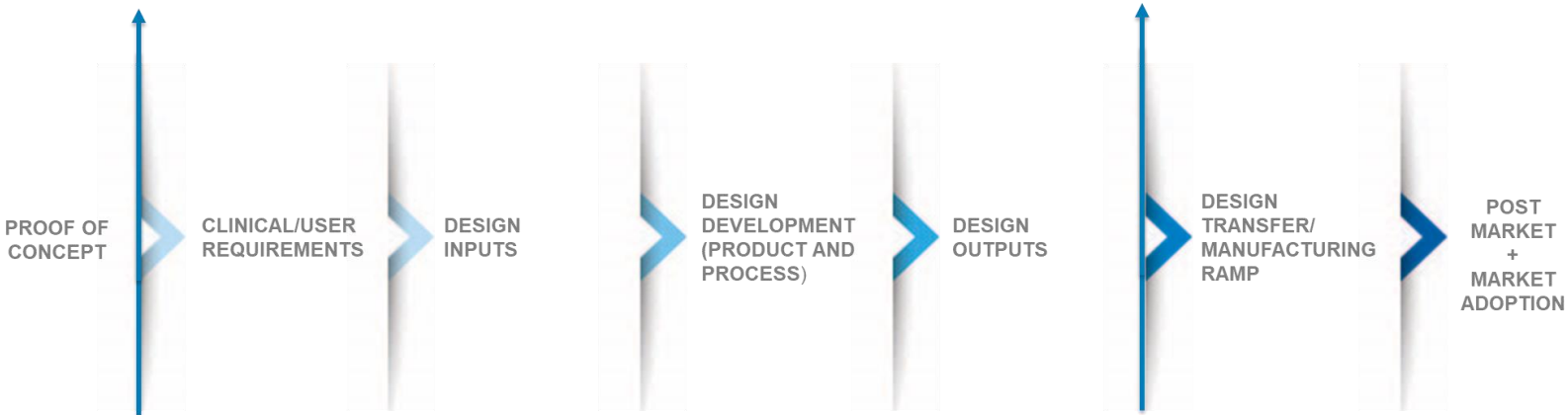
## COMPANY

Early stage medical device company focused on bringing to market novel minimally invasive therapies for CLTI patients globally



PROJECT KICK-OFF

SUBMISSION



PROOF OF CONCEPT

CLINICAL/USER REQUIREMENTS

DESIGN INPUTS

DESIGN DEVELOPMENT (PRODUCT AND PROCESS)

DESIGN OUTPUTS

SUBMISSION

DESIGN TRANSFER/ MANUFACTURING RAMP

POST MARKET + MARKET ADOPTION

CLI PROCEDURE SYSTEM

