

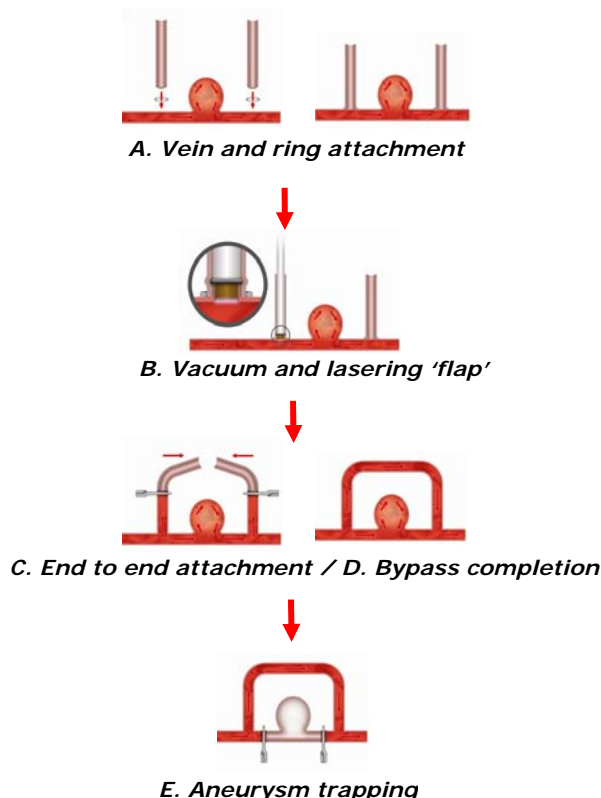
## Background information on the ELANA Study

### Introduction

ELANA, Eximer Laser-Assisted Nonocclusive Anastomosis, is a technique using an eximer laser/catheter system for intracranial bypass surgery of the brain. The ELANA technique has been developed by Professor Tulleken from the University Medical Center (UMC) in Utrecht, the Netherlands.

Transplanted conduit bypass emerged as a valuable technique for the treatment of giant aneurysms, certain skull base tumors, or special cases of cerebrovascular diseases in the 1980's, but relied upon a significant period of flow arrest for creation of the bypass. This period of flow arrest is associated with an increased risk of stroke.

The ELANA technique is designed to allow the operating surgeon to connect a bypass graft to a major intracranial artery without any arrest of flow or occlusion time (Figure 1).



### ELANA Study

The ELANA technique has been used in Europe since 1993 in approximately 350 clinical procedures. The objective of this prospective, nonrandomized, international, FDA approved, multi-center Study is to confirm the clinical experience in Europe and demonstrate the safety and efficacy of the Elana Arteriotomy System in creating an intracranial arteriotomy in a nonocclusive manner.

Centers will enroll patients who require a temporary or permanent bypass to be connected to one or more unoccluded intracranial vessel(s) for an established indication and for whom the responsible surgeon feels they cannot be safely treated otherwise e.g., because of a lesion not ideal for coiling or clipping or excision or temporary or permanent occlusion of a vessel without the temporary or permanent creation of a bypass.

### Participating Centers:

- **St. Lukes Roosevelt Hospital**  
New York, NY
- **University of Illinois**  
Chicago, IL
- **University of Arkansas UAMS**  
Little Rock, AR
- **L.M. Miller School of Medicine, University of Miami**  
Miami, Florida
- **University of Texas Southwestern Medical Center**  
Dallas, Texas
- **Department of Neurosurgery, Charité Universitätsmedizin**  
Berlin, Germany
- **Helsinki University Hospital**  
Helsinki, Finland
- **University Medical Center Utrecht**  
Utrecht, the Netherlands

### REFERRALS

Physicians within the referral areas of the participating centers are being asked for their help in identifying patients who meet the inclusion/exclusion criteria.

For further information on the ELANA Study please contact Felix von Coerper at

[felix@elana.com](mailto:felix@elana.com) or visit [www.elana-study.com](http://www.elana-study.com). For Clinical Case Discussions, please visit [www.forum.elana.com](http://www.forum.elana.com).

Study Sponsor: Elana Inc., a subsidiary of Elana bv. Yalelaan 44, 3584 CM, Utrecht, The Netherlands.

**Caution:** Investigational Device, Limited by Federal (US) Law to Investigational Use.

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