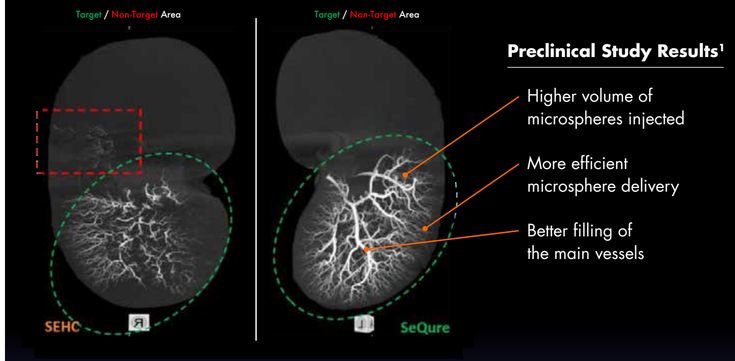
SEQURE®

Reflux Control Microcatheter

Designed to Help Reduce the Reflux of Embolic Material[1]

The preclinical study showed that the SeQure® reflux control microcatheter delivered more microsphere volume while reducing the risk of non-target embolization.[1]



Preclinical Study Results[1]

- Higher volume of microspheres injected
- More efficient microsphere delivery
- Better filling of the main vessels

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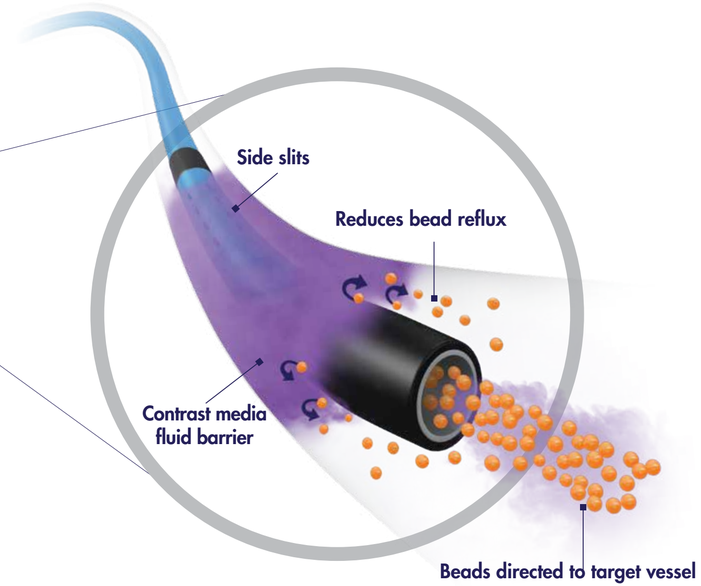
*Preclinical study was sponsored by Guerbet Group.
Study authors: Maleux, De Baere, Sun, Holtzman, Harbater, Balvay, Veil, Rizzitelli, Violas, Robert, Robic, Seron, Corot.

Fluid Barrier Technology for Flow-Directed Embolization

The SeQure® reflux control microcatheter with distal micro side slits utilizes flow dynamic principals to create a filtered contrast media fluid barrier and direct beads to the target vessel, allowing interventional radiologists to have more control over their embolization procedures.



Reduced Non-Target Embolization and Increased Targeted Delivery with SeQure® Microcatheter Demonstrated in Swine Model Study[1]

STUDY OBJECTIVES

A. To evaluate the performance of the SeQure® reflux control microcatheter delivering particles to the target area versus non-target area in vitro and in vivo on a swine pre-clinical model.

B. To visualize and quantify the amount of microspheres delivered in the target site versus the non-target site; calculate the target/non target ratio.

C. To compare the performances of SeQure® reflux control microcatheter versus a standard end-hole catheter.

STUDY LIMITATIONS

The use of an automatic injector for the microspheres' administration allowed the standardization of the injection but is not representative of the clinical practice. A study with a manual injection closer to clinical experience will follow this first preclinical test.

Results of the preclinical study were based on a swine model which presents a limitation in the translational aspect of the conclusion. Further exploration in a pathological model is needed.

STUDY METHODS

The target vessel in the kidneys of thirteen pigs were identified using 2.4 Fr (n = 7) or 2.7 Fr (n = 6) microcatheter (SeQure® versus Standard End-Hole Catheter). Evans Blue solution was injected to stain the selective area of injection followed by the injection of 75/150 µm radiopaque microspheres suspended in 50/50 Iobitridol 300/NaCl solution (1 mL of beads in 10 mL of solution). Injection was performed by an automatic injector with flow rate of 8 mL/min. End point was obtained via reflux of contrast in non-target vessel at the second visible time (according to clinician experience). Angiography was performed with a 4/5 Fr catheter of the whole kidney post embolization.

Ex-vivo analysis was completed using µCT ex vivo for quantitative analysis of target embolization, non-target embolization, ratio target/non-target embolization; Evans Blue detection was for determining the target area of injection.

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For more information, please contact us at 1-877-729-6679 or medical.liaison.na@guerbet.com

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.

INDICATIONS FOR USE: The SeQUre® microcatheters are intended for the infusion of contrast media into all peripheral vessels. The SeQure® microcatheters are also intended for drug infusion in intra-arterial therapy and infusion of embolic materials. The SeQure® microcatheters should not be used in cerebral vessels.

1. Maleux et al. Reduced Non-Target Embolization and Increased Targeted Delivery with SeQure® Microcatheter Demonstrated in Swine Model. Presented at RSNA 2019.
2. Maleux et al. Reduced Non-Target Embolization & Better Delivery with an Innovative Reflux Control Microcatheter: Mechanisms of Action and Clinical Application in Four Swine. Presented at CIRSE 2019.

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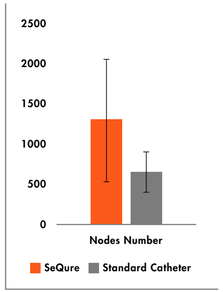
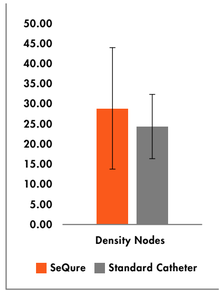
Preliminary Data from the Preclinical Study[2]

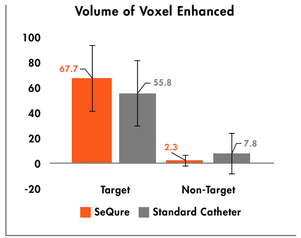
Preliminary results on the right demonstrate that the SeQure® reflux control microcatheter showed higher node filling when compared to a standard end-hole microcatheter.

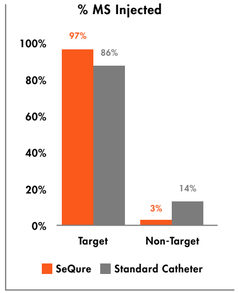


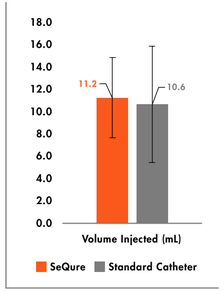


Preclinical Results from the Preclinical Study[1]

Preclinical results below demonstrate that the SeQure® reflux control microcatheter produced a higher volume of microsphere (MS) delivery in the target area (and increased microspheres injected) when compared to a standard end-hole microcatheter.







STUDY OUTCOMES

The photos below demonstrate that the SeQure® reflux control microcatheter produced better **filling of the main vessels, higher volume of microspheres injected** (green circle), and **less non- target embolization** (red box). **Ex-vivo marking** (orange circle) demonstrates more targeted fill area with the SeQure® reflux control microcatheter versus a standard end-hole microcatheter.

- Better filling of the main vessels
- Higher volume of microspheres injected
- Less non-target embolization
- More distal penetration of microspheres
- More efficient microsphere delivery
- Predictability of the treatment