

DIREXION™ Torqueable Microcatheter

REPOSITION WITHOUT THE WIRE

Key practical benefits & Savings
implication for a steerable microcatheter



Safety and Efficacy Vessel Catheterization with the New Steerable Microcatheter Direxion compared with a Standard Microcatheter : A Prospective, Preclinical Trial

Cardiovascular Interventional Radiology (2014) 37:1041–1046 , Oliver Dudeck – University Magdeburg, Germany

Boston
Scientific

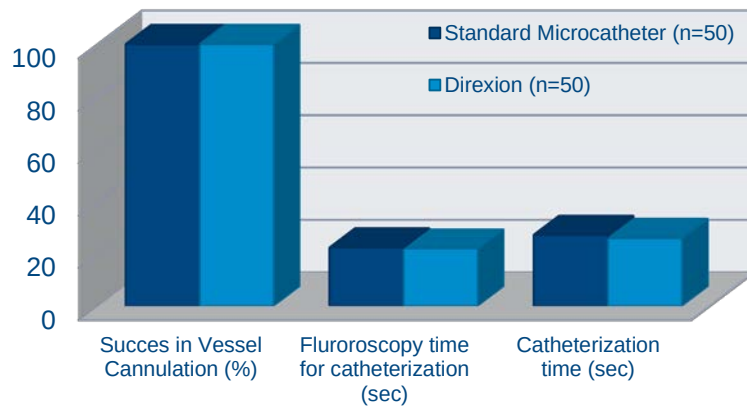
Study purpose and methodology

- 2 swines
- 100 target vessels of max 3mm diameters
- Side branches of hypogastric, superficial and deep femoral arteries.
- Randomization with Direxion™ Hi-Flo J-tip and standard microcatheter with similar steam shape.
- Microcatheters were inserted with the guidewire and positioned at the end of the guiding catheter
 1. Guidewire assisted
 2. Without guidewire assistance

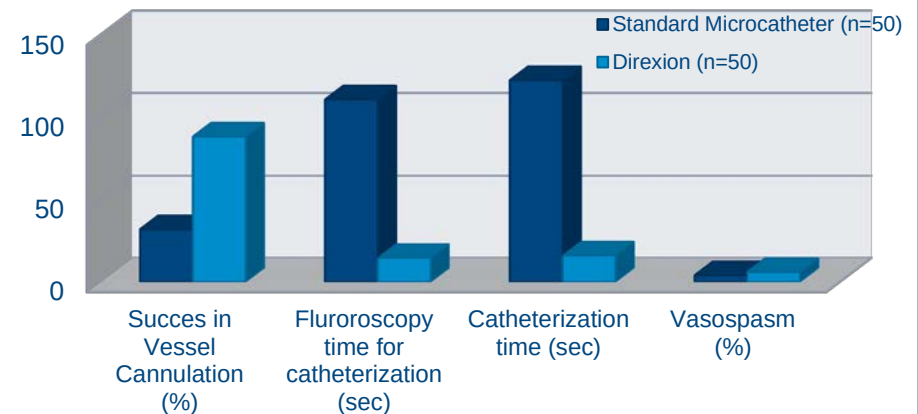
Catheterizations were evaluated from the tip of the guiding catheter.

Comparison of Guidewire and Guidewireless* vessel catheterization

Guidewire assisted vessel catheterization



Guidewireless* target vessel catheterization



* **Caution:** Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter.

Less time & fluoroscopy

☐ Enhanced vessel selectivity

☐ Repositioning

o Secondary catheter manipulation

- ☐ Time and material savings in **several target vessels embolization**.
- ☐ **Microguidewire reinsertion when using liquid embolics** and reinsertion is precluded due to lumen being filled with Glue or Onyx.
- ☐ **Microguidewire reinsertion in Radioembolization procedures** where a need for different catheter positions with increasing risk of contamination.

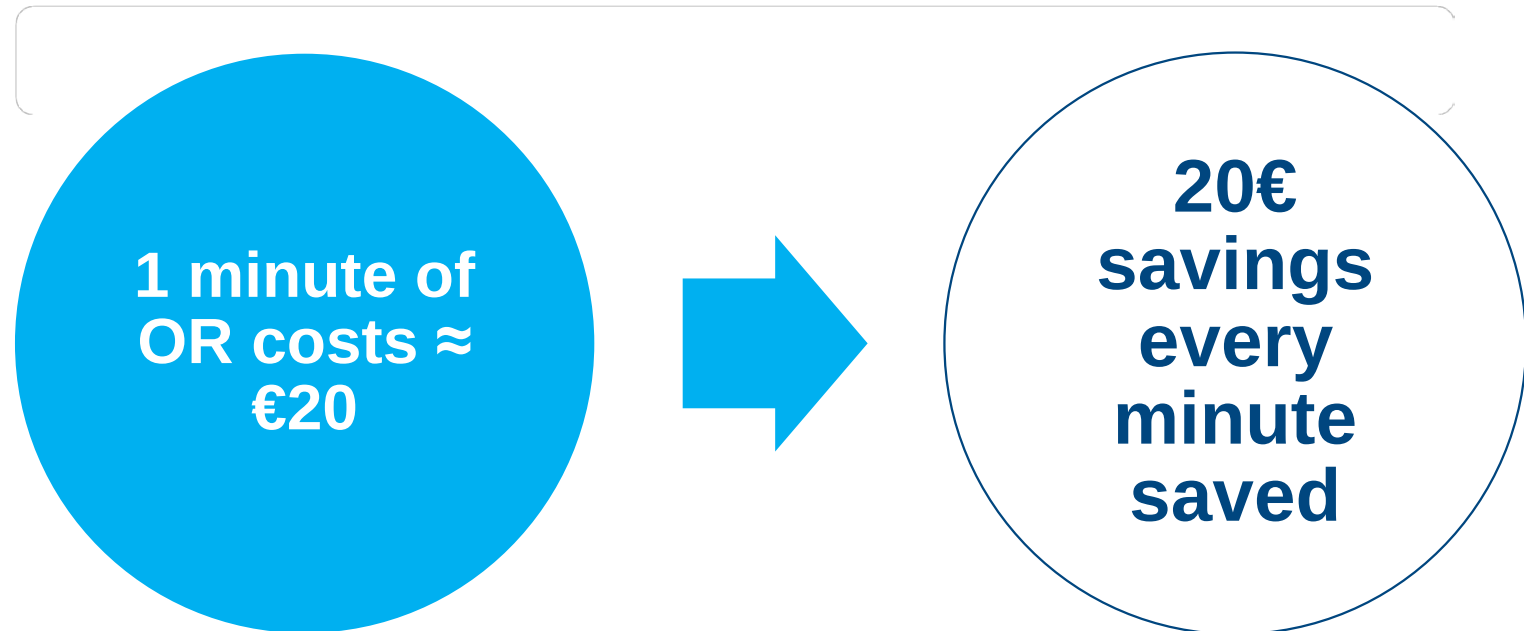
o Stable platform for coil deployment*

- ☐ to help **maintain position within the aneurysm**
- ☐ facilitates **redirection of coils**
- ☐ allowing for **more control over the positioning and packing**.

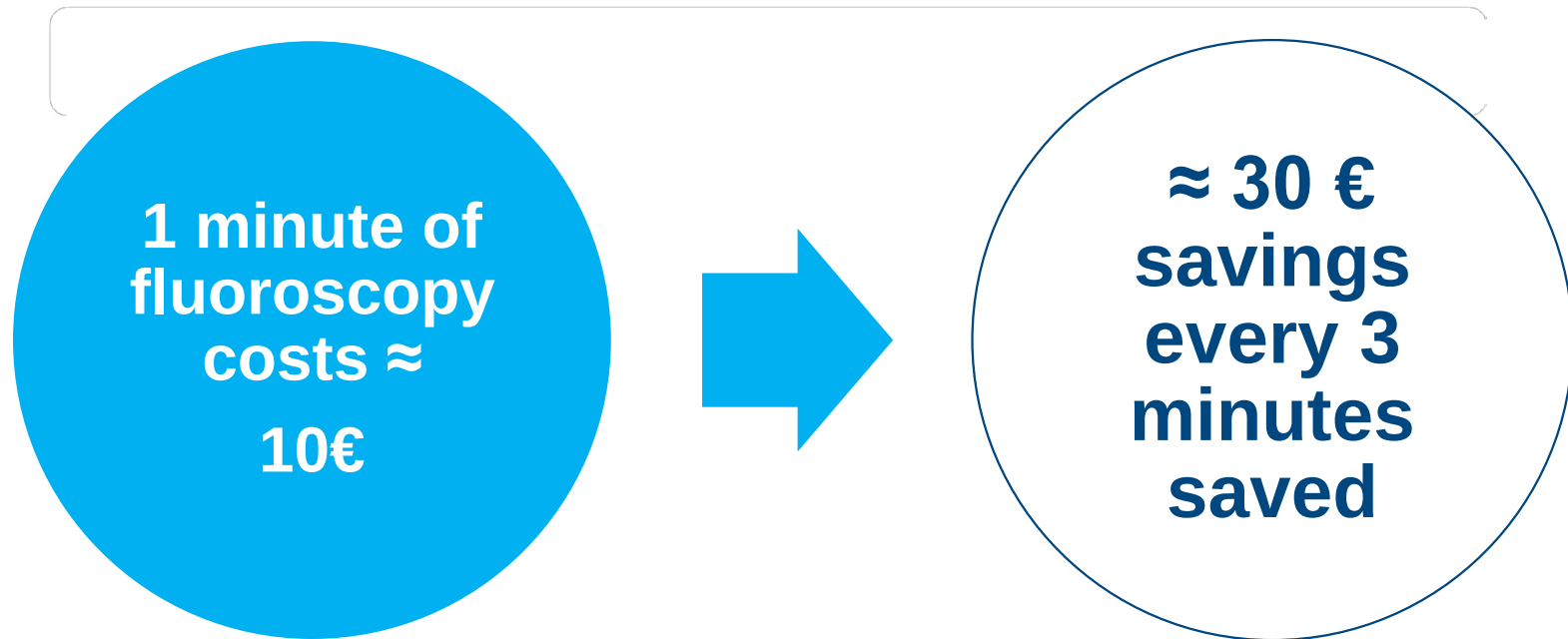
- ☐ Possibility to reposition the catheter into the targeted vessel when kicked-out of the vessel to complete coil delivery

* The Direxion Hi-Flo microcatheter is not designed for the delivery of embolic coils.

Cannulation time is affecting the **procedure's cost** by increasing the operative room **(OR) time**



- Average fluoroscopy time is 10-13 min in standard procedures but it can be **up to 60 minutes in complex procedures**
- There is a direct relation between PCI costs and fluoroscopy time according to procedure **complexity and number of target vessel**



"Fearon WF et al; Circulation. 2010 Dec 14;122(24):2545-50.Economic evaluation of fractional flow reserve-guided percutaneous coronary intervention in patients with multivessel disease."

"Can J Cardiol. 2010 Aug-Sep;26(7):e218-24.Late outcomes following percutaneous coronary interventions: results from a large, observational registry.Appleby CE1,"

Catheterization technique was significantly faster with the Direxion compared with guidewire-assisted vessel catheterization with regular catheter :
16.1 ± 14.4 sec compared with 27.1 ± 24.7 sec (p = 0.011)

	Regular Catheter	Direxion	Difference (sec)	Difference (min)	Cost per min	Savings with Direxion
Success of vessel cannulation	32%	88%	56%			
Fluoroscopy time	110,6	16,1	94,5	2	10€	16 €
Catheterization time	122,4	16,1	106,3	2	20€	35 €
Total savings						51 €

That's « easy case» scenario = Single easy target vessel occlusion



Additional savings in : complex cases, several target vessels occlusion, cases involving Liquid embolics or Y-90.

Increasing the fluoroscopy time implies an **increased risk of radiation adverse effects**

The adverse events related to radiation exposure are very dangerous for patients and operators and could have a strongly impact on healthcare costs.

Radiation Side effects

Stochastic (Random) Effects:

- Cancer
- Mental Retardation
- Genetic Effects

Deterministic Effects:

- Sterility
- Cataracts
- **Skin Erythema**
- Hemopoietic Syndrome
- Gastrointestinal (GI) Syndrome
- Central Nervous System Syndrome

<http://www.icrp.org/>

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