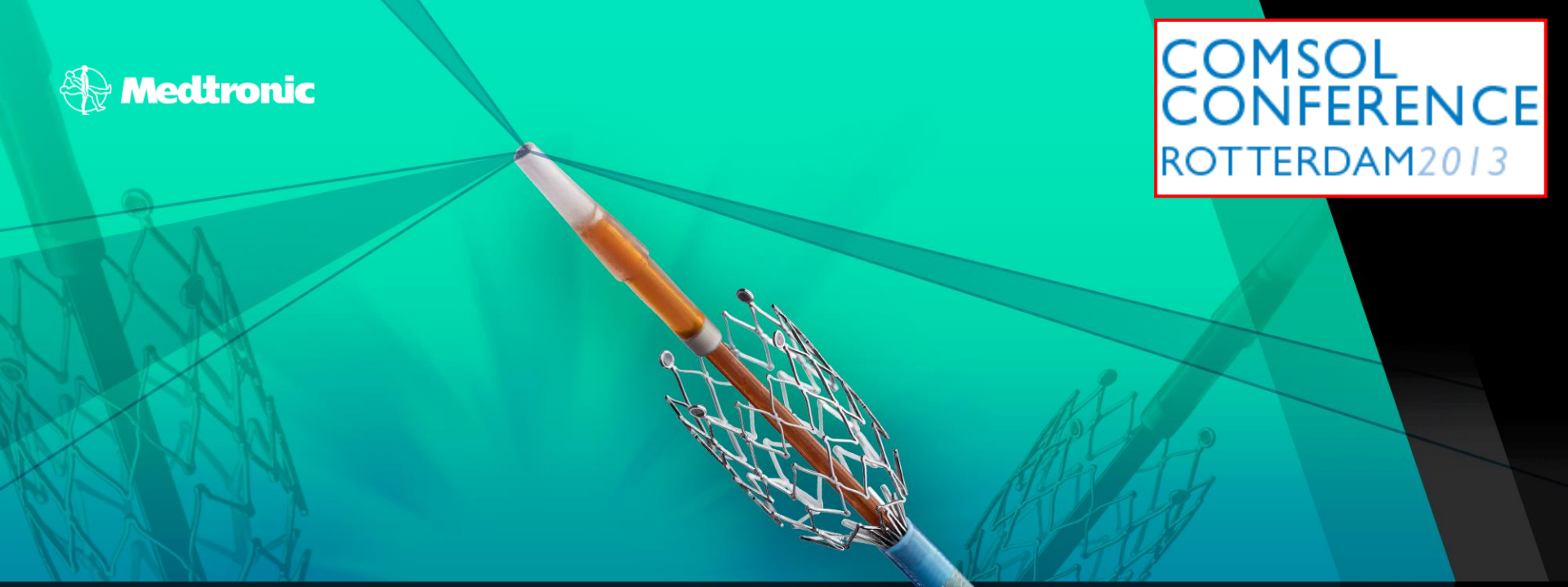

# Pushability Model of a Microcatheter for Intravascular Procedures

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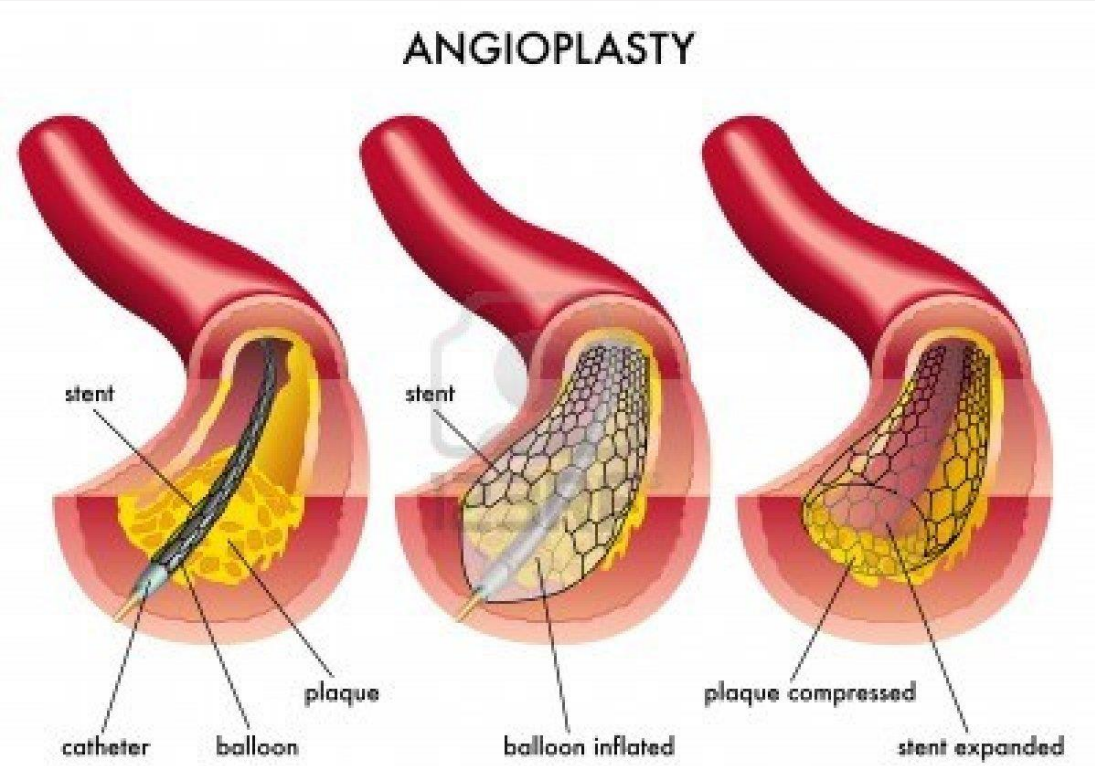
[1]MEDTRONIC Invatec S.p.A., Roncadelle, BS, Italy

# Percutaneous Transluminal Angioplasty (PTA) PROCEDURE

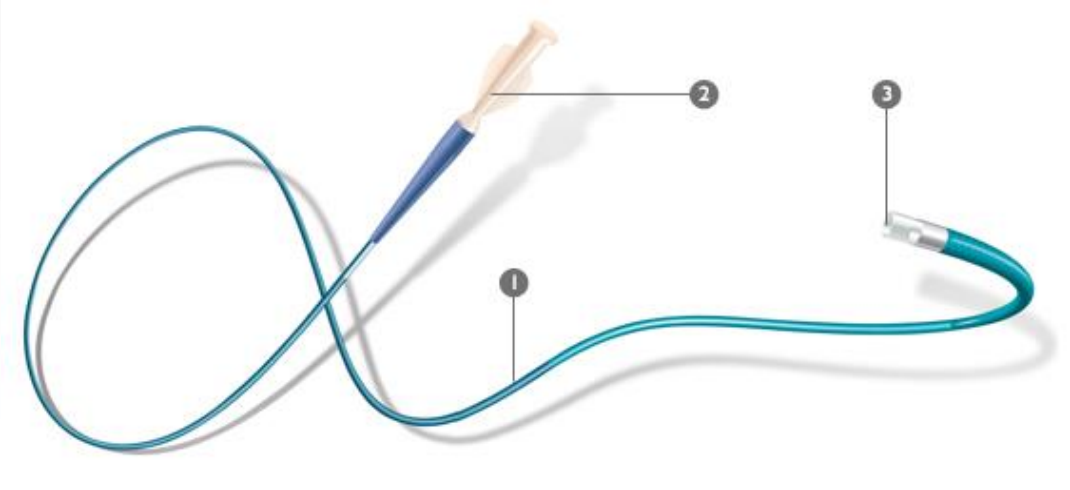



In peripheral arteries (legs) the plaque cannot be crossed only with the guidewire (GW) due to high calcification and low GW stiffness and ‘push’ force.

# MICROCATHETER: usage

A microcatheter is a single-lumen device that can be loaded on the GW in order to track it to the target lesion. The **TRACK FORCE** (TRACKABILITY) needed to reach the lesion should be as low as possible.




The microcatheter is used to help the physician to cross the lesion, previous to the balloon dilatation/stenting, giving mechanical support to the GW and enhancing its ability to transmit **PUSH FORCE** (PUSHABILITY) to the occlusion.

# MICROCATHETER: possible constructions

Device features:

- single-lumen
- Typical outer diameter (OD) ranges from 1.30 mm (proximal shaft) to 0.70 mm (distal tip).
- very different design architectures, for different shaft stiffness:

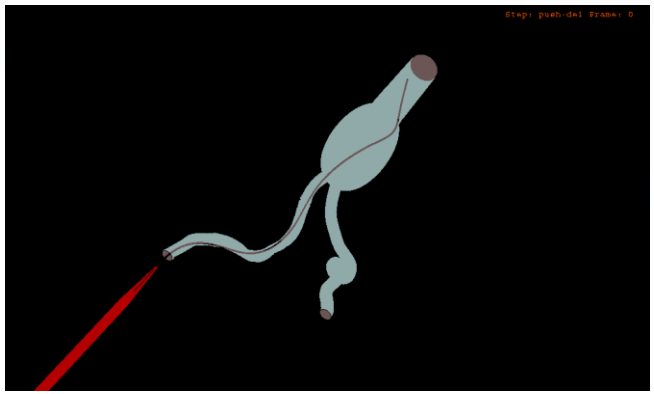
# MICROCATHETER: design targets

Especially for peripheral indications the microcatheter design is a TRADEOFF between…

…**TRACK FORCE** (TRACKABILITY) as low as possible… → Very flexible/floppy construction

…and…

… **PUSH FORCE** (PUSHABILITY) as high as possible. → Very stiff construction



# MICROCATHETER: chosen construction

In order to achieve…

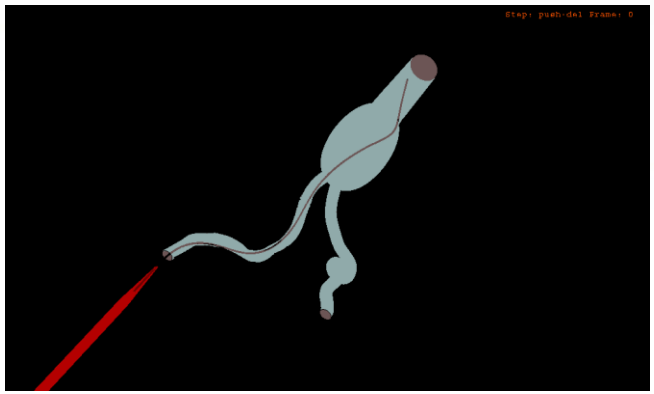
…**TRACK FORCE** (TRACKABILITY) as low as possible…

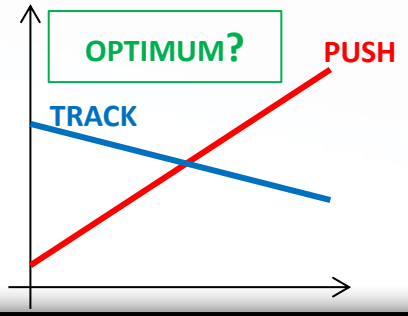
→ **Polymeric** material choice

…and…

… **PUSH FORCE** (PUSHABILITY) as high as possible.

→ Optimized shaft **OD transition** from proximal ‘high’ to distal ‘low’



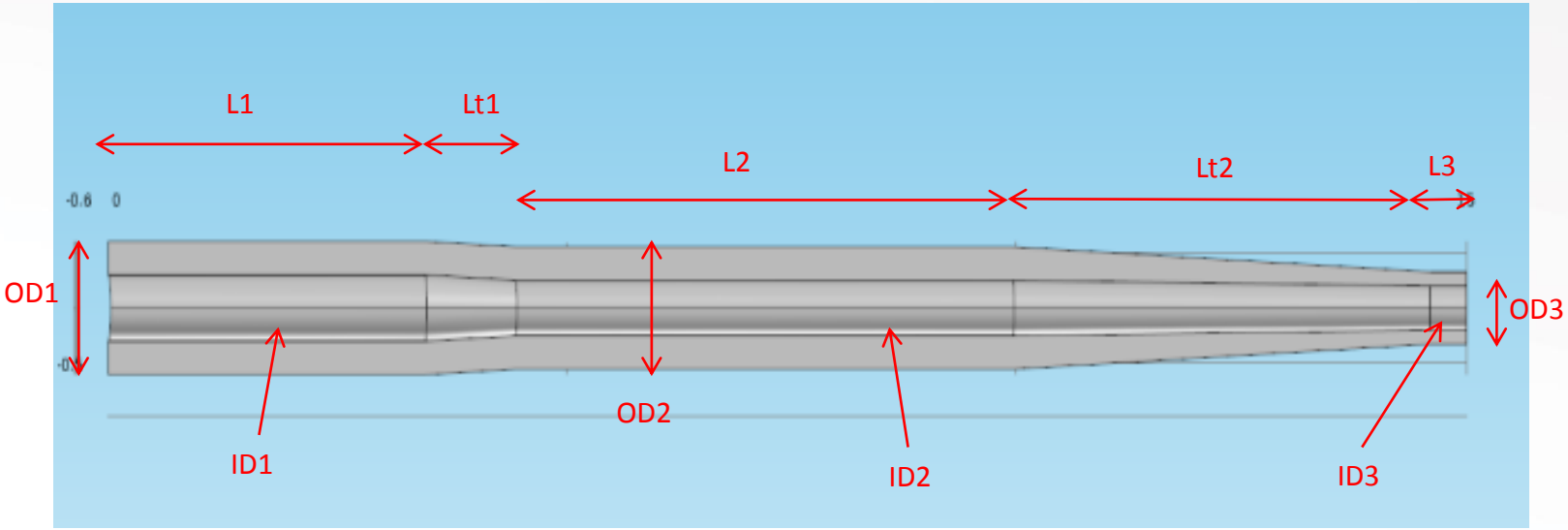


# MICROCATHETER: freezed design

The same as the main competitors, MEDTRONIC device was thought to be a very simple, ‘low cost’ product, but with high performance/price value.

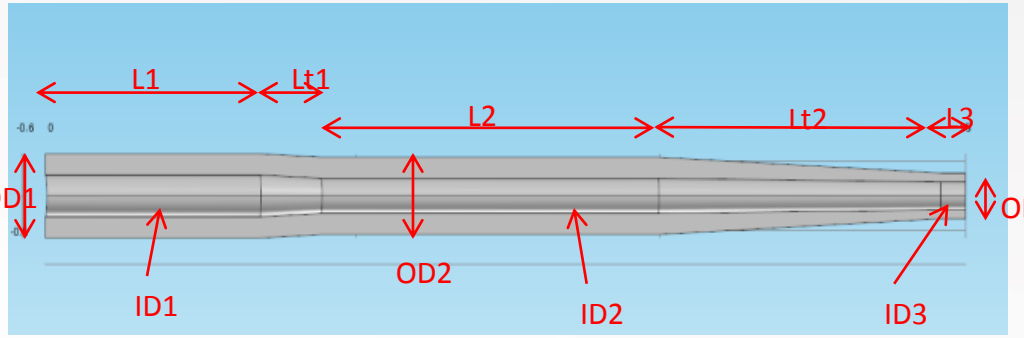
The main feature is a **bumped shaft-tube design** with a **property compound resin** developed in-house.

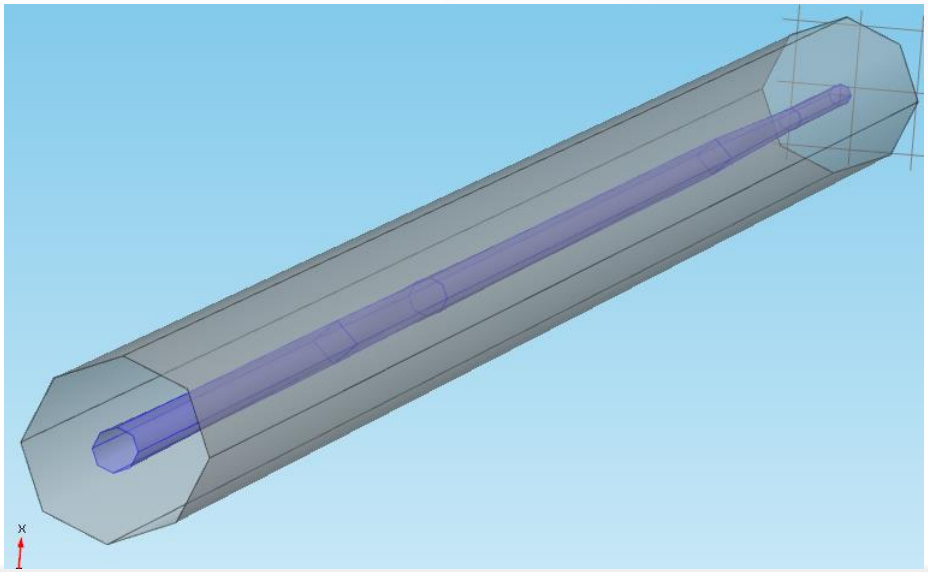



(overall length is fixed to 1500 mm)

# MICROCATHETER: FEA settings - GEOMETRY

SOLID geometry was initially evaluated, but to reduce computational burden **SHELL geometry** was chosen. Design is defined by **10 parameters**, and can be easilly created in COMSOL.



Parameters | Model Library

**Parameters**

| Name | Expression | Value | Description |
|---|---|---|---|
| OD1 | 1.22[mm] | 0.0012200 m | Proximal OD |
| OD2 | 1.10[mm] | 0.0011000 m | Median OD |
| OD3 | 0.70[mm] | 7.0000E-4 m | Distal OD |
| ID | 0.46[mm] | 4.6000E-4 m | |
| Ltot | 1700[mm]/k | 1.7000 m | |
| L1 | 450[mm]/k | 0.45000 m | |
| L2 | 700[mm]/k | 0.70000 m | |
| L3 | 140[mm]/k | 0.14000 m | |
| Lt1 | 205[mm]/k | 0.20500 m | |
| Lt2 | (Ltot-L1-Lt1-L2-L3) | 0.20500 m | |
| k | 1 | 1.0000 | |

**Shell variable thickness**

*((z+w2)<=L1)*(0.38[mm])+(((z+w2)>L1)*((z+w2)<=(L1+Lt1)))*(-0.000293*((z+w2)-L1)+0.38[mm])+ .....*

# MICROCATHETER: FEA settings - MATERIALS

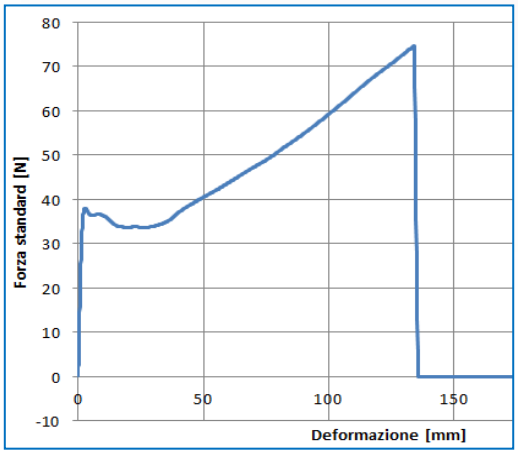
The external tube (ID = 5 mm) represents a peripheral anatomical model and has been considered perfectly rigid (as in bench tests).

For initial studies, a common Pebax linear elastic material model was used for the catheter shaft…:

**Material Contents**

| Property | Name | Value |
|---|---|---|
| Density | rho | 1150[kg/m^3] |
| Young's modulus | E | 0.6e9[Pa] |
| Poisson's ratio | nu | 0.3 |

Finer material characterization is ongoing (elasto-plastic / hyperelasto-plastic model):

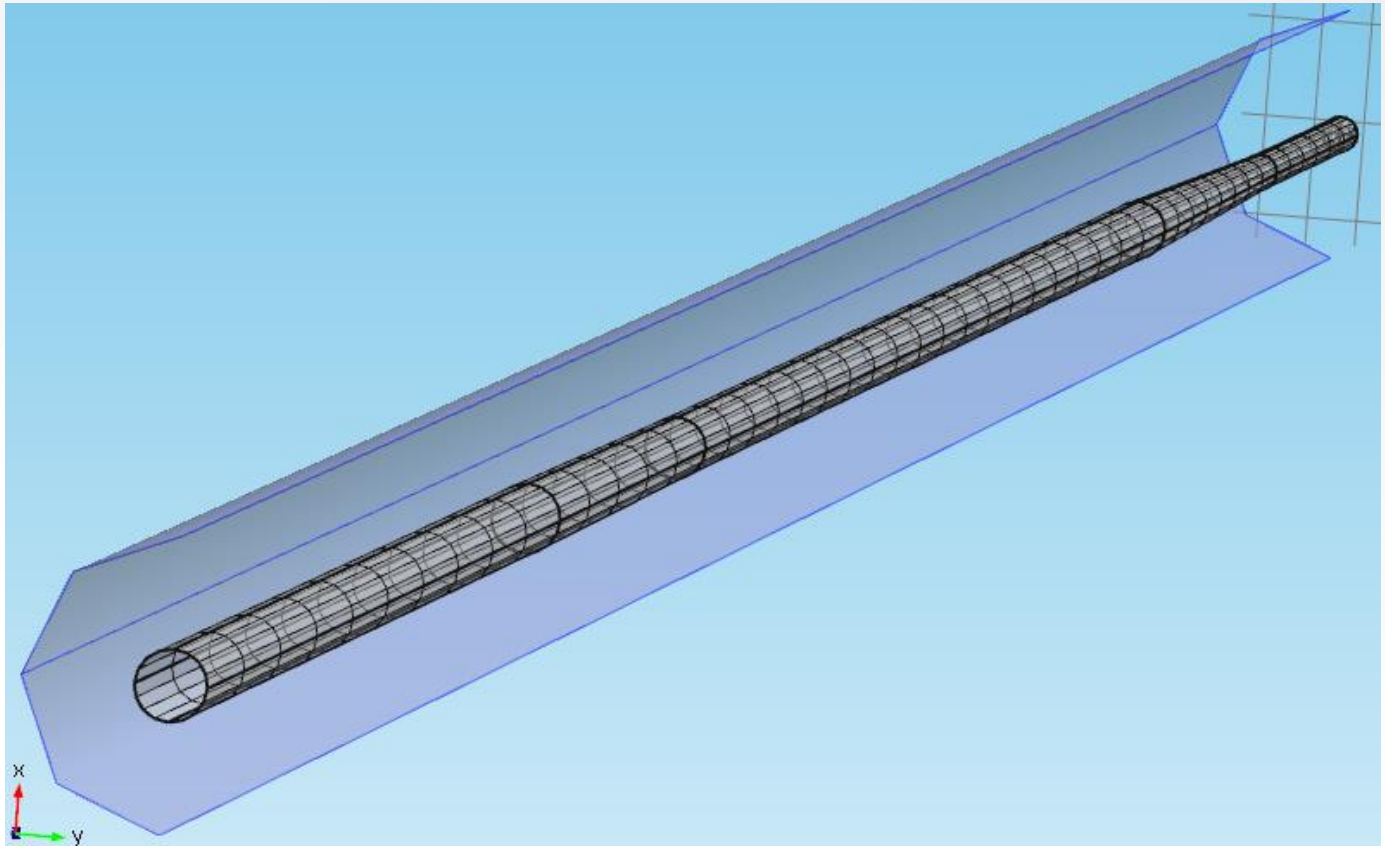


Medtronic

# MICROCATHETER: FEA settings - MESH

**For SHELL geometry:** square quadratic elements were used.

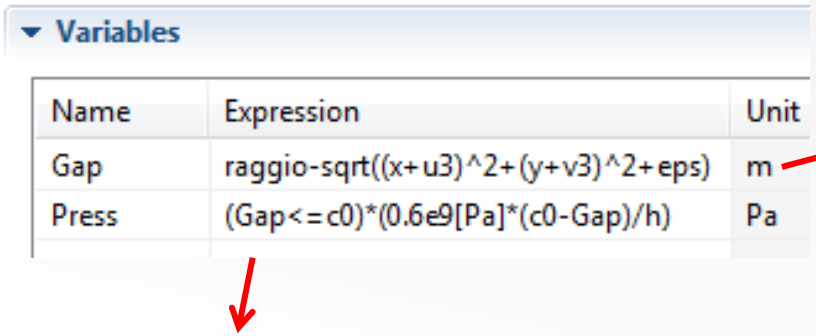



The outer tube is for representation purposes only, since **no contact can be defined with SHELL elements**

# MICROCATHETER: FEA settings – CONTACT

Since no contact can be defined with SHELL elements, contact has been MANUALLY DEFINED:



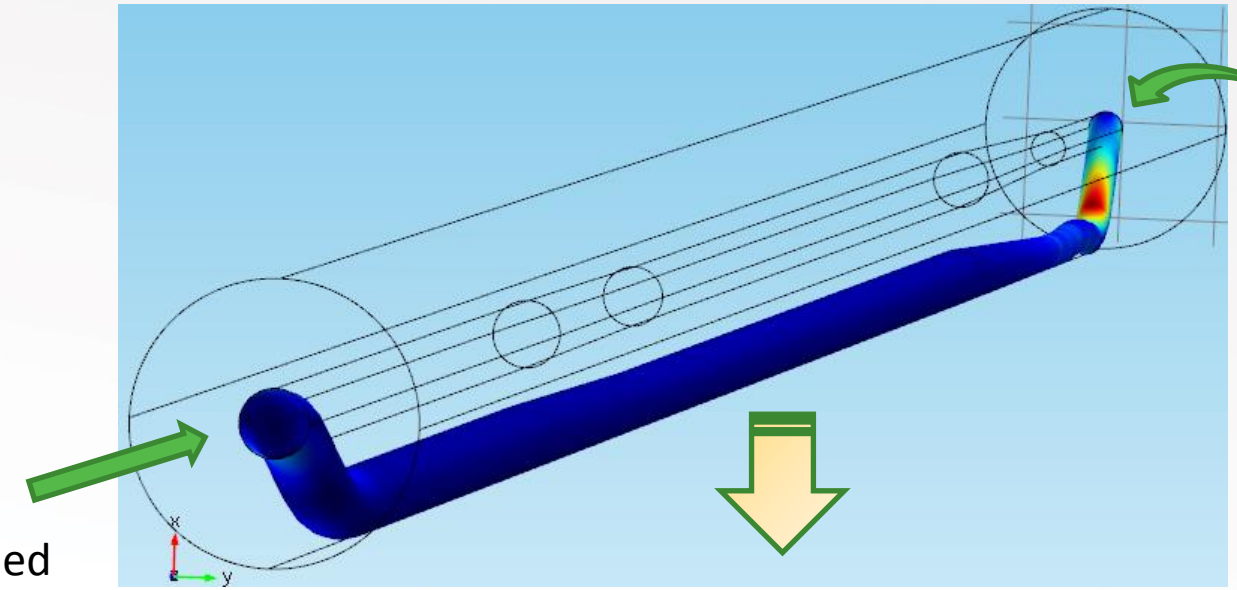

Variable '**Gap**' has been defined as the distance between the outer suface of the shell-catheter and the inner surface of the anatomical model (the straight external rigid tube).

If 'Gap' becomes lower than the defined parameter c0 (= 1e-5 m) a pressure variable '**Press**' is generated on the outer surface of the shell-catheter, according to a **standard contact algorythm (with penalty factor)**.

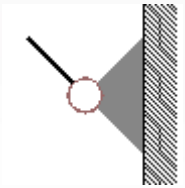
Hence, contact is a surface pressure applied to the shell catheter structure, when it 'touches' the anatomical model.

# MICROCATHETER: FEA settings – BOUND. COND.

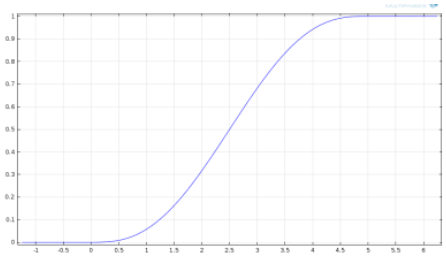
A **TIME-DEPENDENT** analysis has been set up, with…



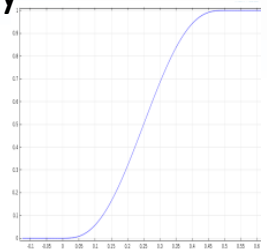
…and a rigid **connector** on the distal edge (catheter tip)



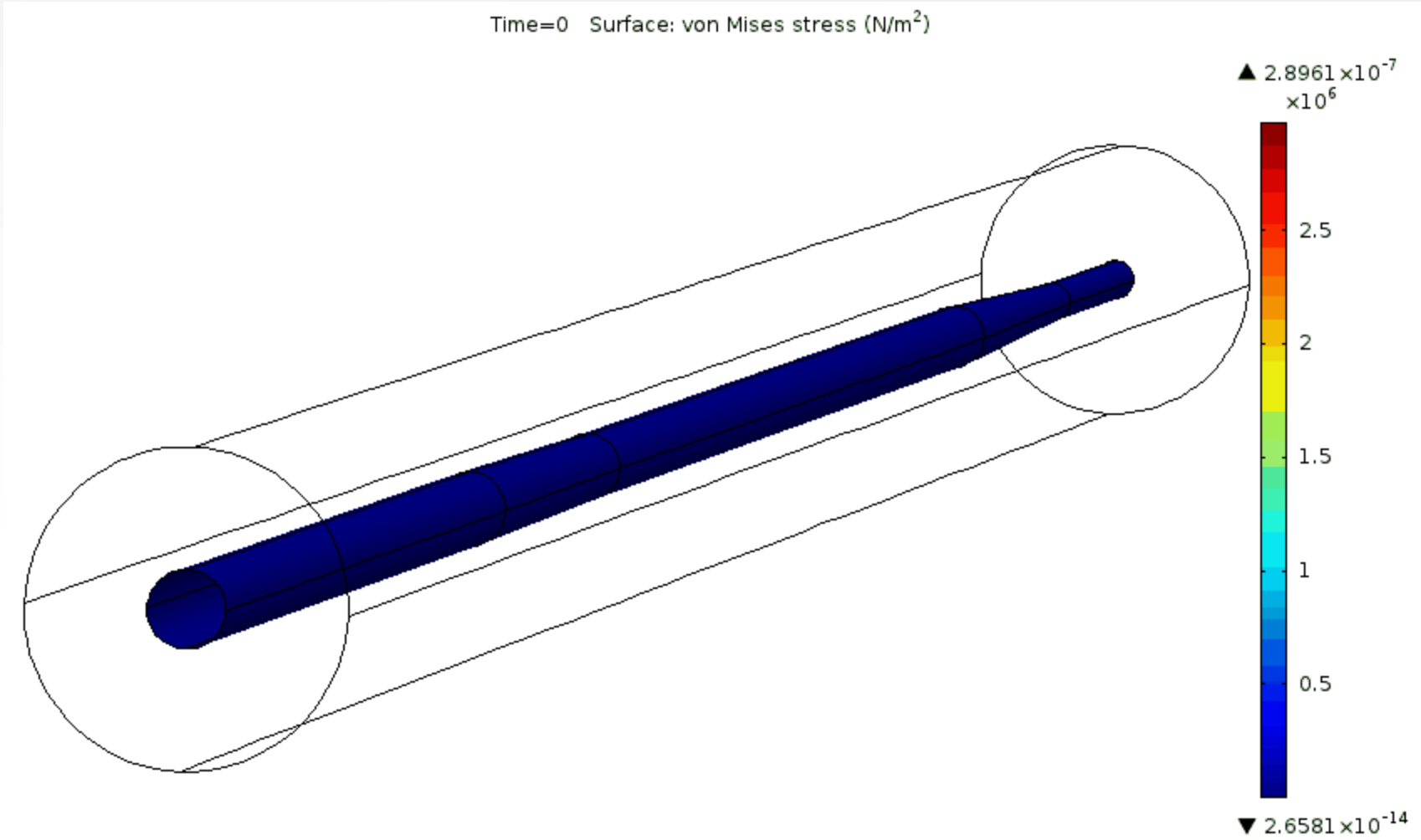
…controlled **displacement** on proximal end (T=5 s),



…**gravity** effect as body load,

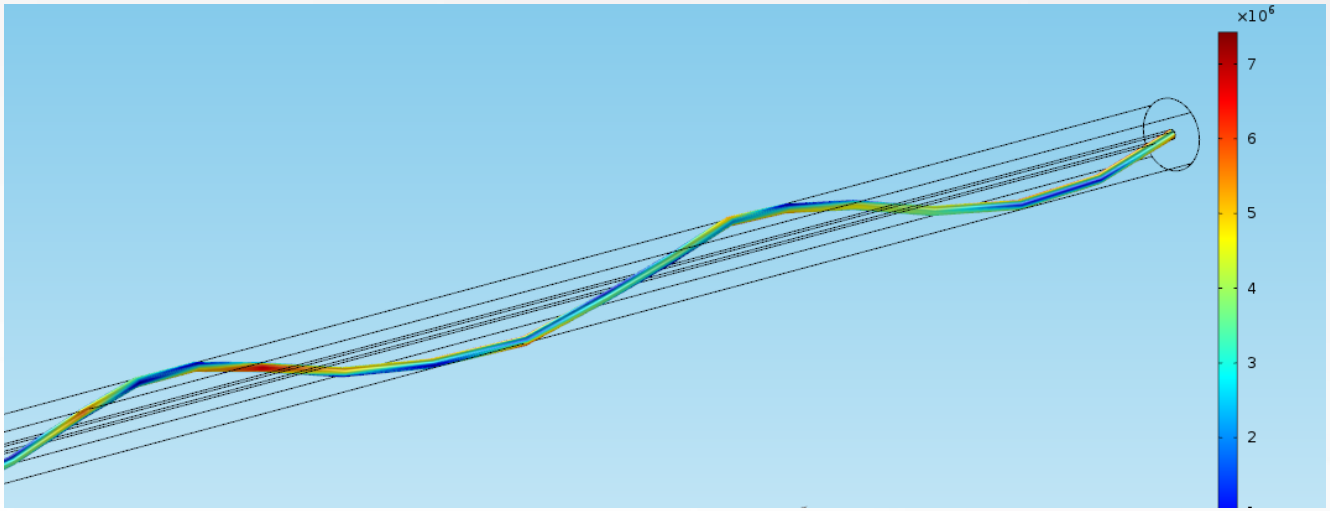


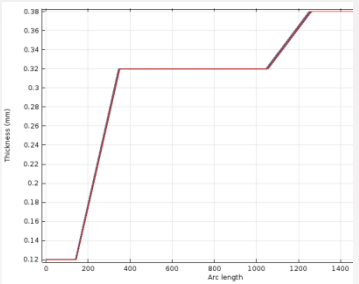
# MICROCATHETER: FEA RESULTS



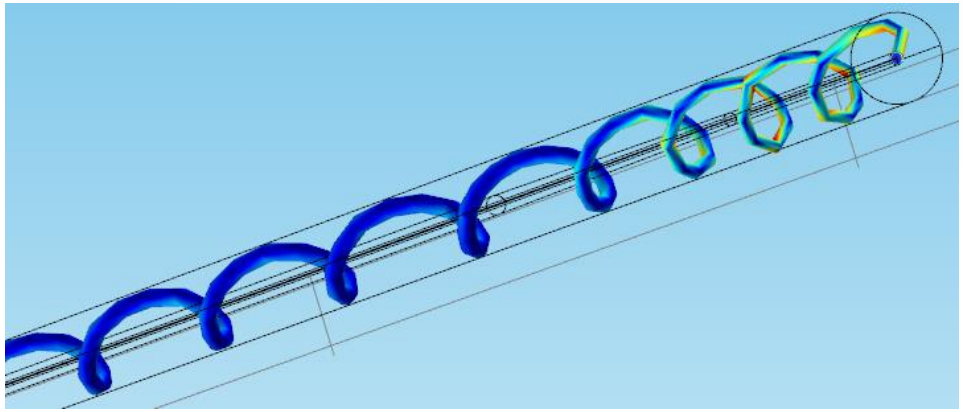
# MICROCATHETER: FEA RESULTS

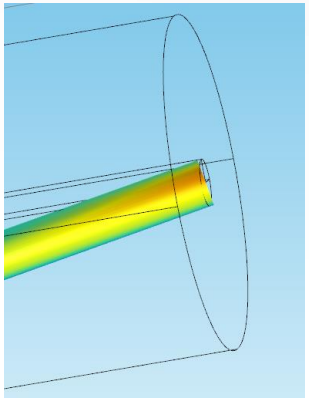
SHAPE of DISPLACEMENT is very similar to bench observations:




Shell thickness was captured



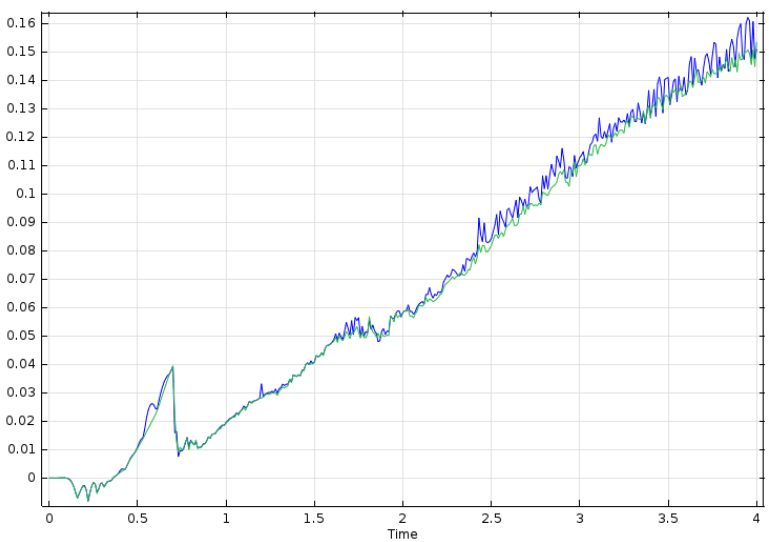


Rigid connector

# MICROCATHETER: FEA RESULTS

**VALUES of PUSH FORCE** are still far from bench measurements…

15 – 20 grams
Vs.
200-250 grams



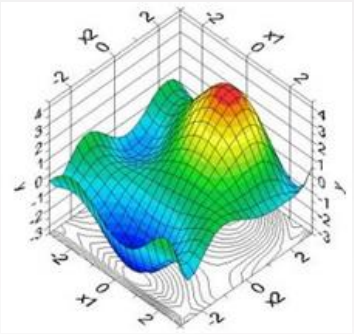

…probably due to:

- absence of the guide-wire in the simulation
- material properties to be better refined (propetary resin compound should be characterized)

# MICROCATHETER: CONCLUSIONS

Thanks to COMSOL, this model can be done totally parametric in geometry and boundary conditions.

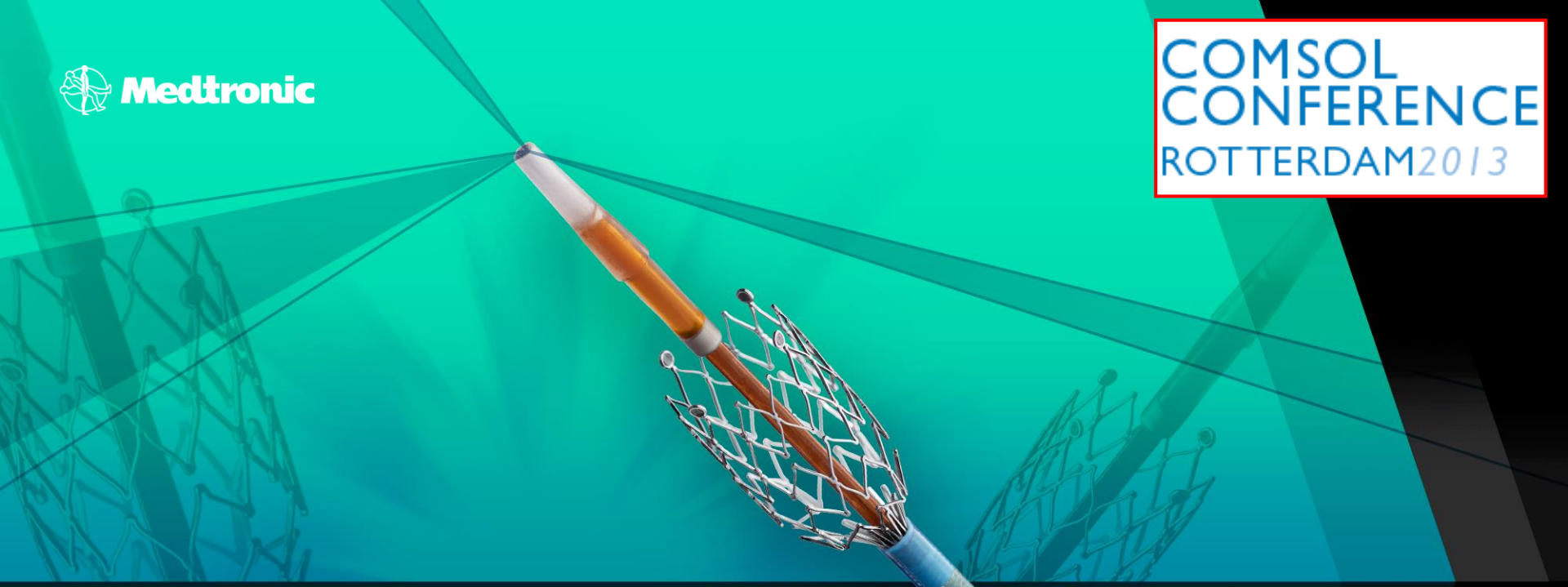
Hence, parametric sweep, sensitivity or real optimization could be further investigated for optimization of Microcatheter design (MIN TRACK force, MAX PUSH force).



**NEXT STEPS:**

- Refine material model
- Add the GW to the simulation, with manual definition of inner contact
- Explore the possibility to define contact within a more complex anatomical model (w. tortuosities) to better measure TRACK force.
- Reduce computational time for optimization problem.

## Questions?



# Pushability Model of a Microcatheter for Intravascular Procedures

## *THANK YOU*

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