

GENIE Catheter™

by Acrostak

A local drug delivery catheter for anti-stenosis drug.

The **GENIE Catheter™** is a new «local drug delivery (LDD) catheter» designed to deliver various liquid therapeutic agents, such as paclitaxel, into the arteries. Using the **GENIE Catheter™**, Physicians have developed the concept of «**GENIE Catheter™ Therapy**» by exposing coronary arteries to low dose (10µM) of paclitaxel to prevent stenosis. This new approach has been described as a potential alternative/complement to Drug Eluting Stent (DES) in specific indications^(a).

As a device **GENIE Catheter™** offers 5 key benefits:

1. The **GENIE Catheter™** is **safe**.
It delivers the drug **without any polymer or additional coating**.
2. The **GENIE Catheter™** is **efficient**.
Liquid drug can reach most of the vessel wall (not only on the struts of the stent).
3. The **GENIE Catheter™** is **versatile**.
One can treat a **wide range of locations** (the lesion, the stent edge, and the adjacent vessel segments, ...)
4. The **GENIE Catheter™** is «**non-expensive**».
The same device can be used to treat different lesions during the same procedure.
5. The **GENIE Catheter™** is «**non-traumatic**».
This is a «passive» delivery system which avoids the vascular trauma of plaque crushing and stenting

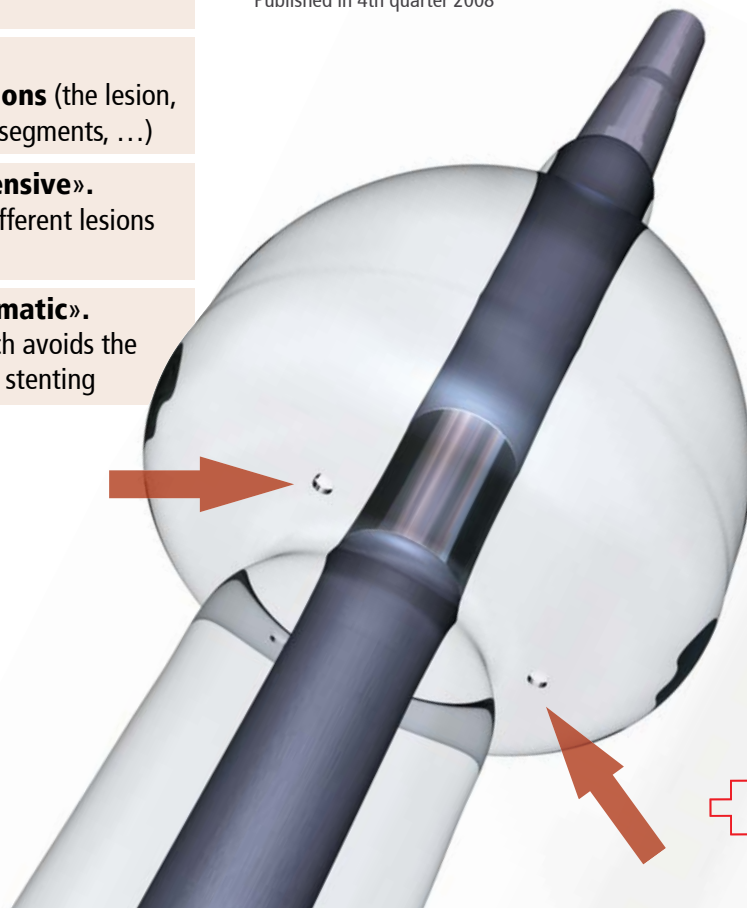
Design of the micro-holes directs the fluid flow parallel to the balloon shaft.

In applications where the risk of stenosis is high (i.e. bifurcations, long lesion, CTO, ISR etc...), or when there are medical or economical concerns about using DES, physicians can still achieve the benefits of a local pharmacological treatment by using **GENIE Catheter™** whilst avoiding long term and expensive anti-platelet treatment.

After animal trials^(a), a clinical study has demonstrated the interest of this «**GENIE Catheter™ Therapy**»: «a limited exposure (during 120") to liquid paclitaxel in coronary arteries is sufficient to inhibit the cell growth process of stenosis». «**LOCAL TAX**» study^(b) was conducted by Dr. C. HERDEG at the University Hospital of Tuebingen, Germany, and involved 204 patients. It compares the use of BMS alone or with concomitant exposure to liquid paclitaxel delivered by the **GENIE Catheter™**, to a Taxus™ DES. «No adverse events and no late thrombosis have been reported».

^a Refer to Dr C. HERDEG publications

^b Published in 4th quarter 2008

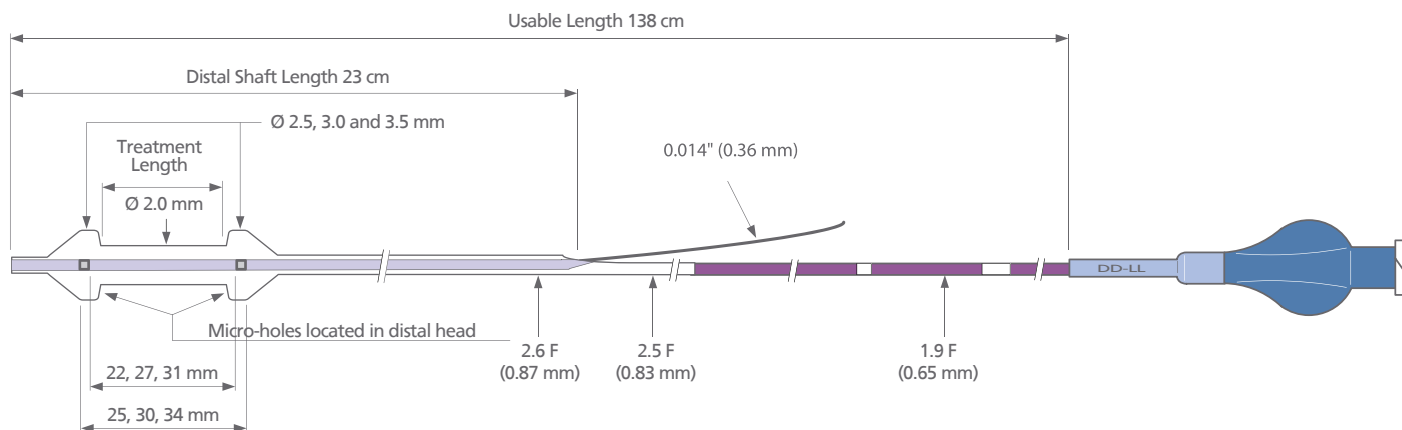
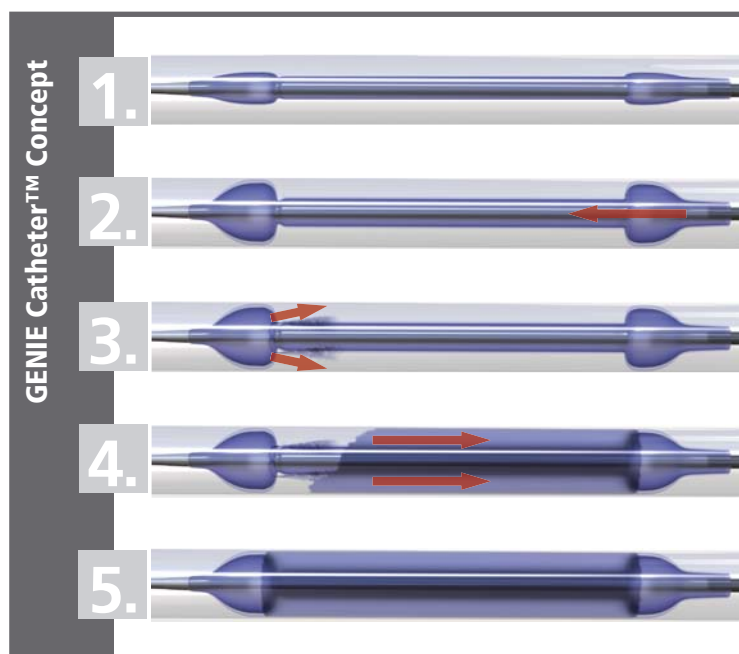


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Acrostak
Devices for interventional applications

GENIE CATHETER™ - TECHNICAL DRAWING**EXTENSIVE DRUG DELIVERY****HOW IT WORKS**

1. Pre-fill the "GENIE Catheter™" with drug solution and purge it.
2. Deliver the "GENIE Catheter™" to the treatment area^(c)
3. Inflate the "GENIE Catheter™" up to 2 atm, directly with the drug solution. The 2 heads block the flow
4. The chamber between the 2 heads is filled up with drug solution through micro-holes
5. After limited exposure, deflate the "GENIE Catheter™" and move to another area or pull back

The **GENIE Catheter™** is available in 3 diameters from 2.5 to 3.5 mm and lengths of 20, 24 and 28 mm. The on-going **GENIE Catheter™** development program also includes devices of larger diameters/lengths for peripheral applications^(c).

^c do not use this balloon for dilatation also refer to section 9.3 "preparation" of the IFU before using the catheter



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ORDERING INFORMATION

Reference	Diameter (mm)	Length (mm)
GENIE Catheter™		
250200320	2.5	20
250240320	2.5	24
250280320	2.5	28
300200320	3.0	20
300240320	3.0	24
300280320	3.0	28
350200320	3.5	20
350240320	3.5	24
350280320	3.5	28