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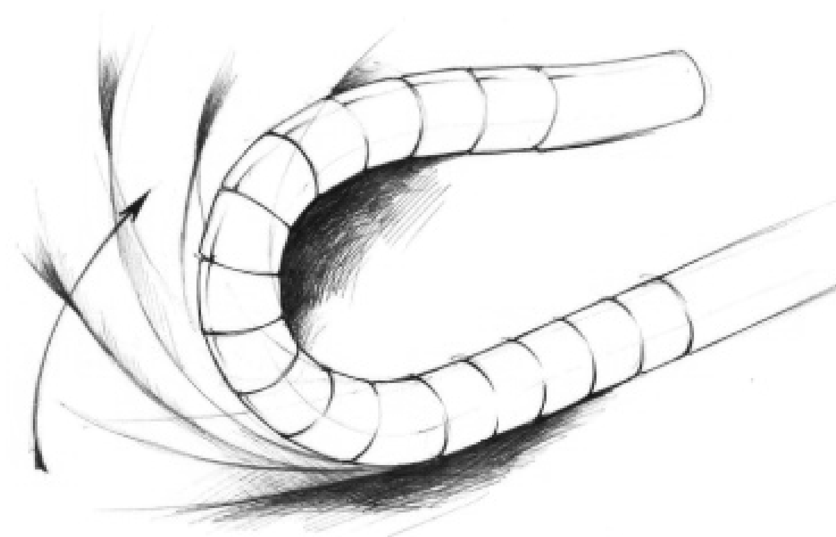
Deflectable & Steerable Catheter Handbook



Terminology Guide & Design Options

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Terminology – Steering v's Deflection

Steerability

This refers to the ability to turn or rotate the distal end of the catheter with like-for-like movement of the proximal section or catheter handle. It is achieved through strong torque transfer along the length of the shaft.

Deflection

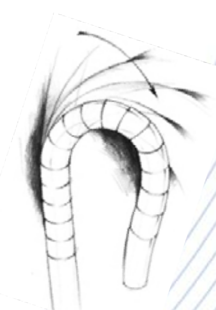
Deflection refers to movement of the catheter tip independent of the rest of the catheter.

Terminology – Catheter Types

Steerable fixed curve catheters

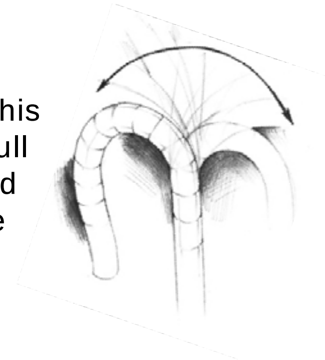
These catheters have a predefined distal curve shape. They have high torque transmission that allows you to turn the tip of the catheter with almost like-for-like rotational movement of the proximal handle. These types of catheters are widely used to access challenging anatomy, during diagnosis, delivery and biopsy etc.

Deflectable catheters (Uni-directional catheters)



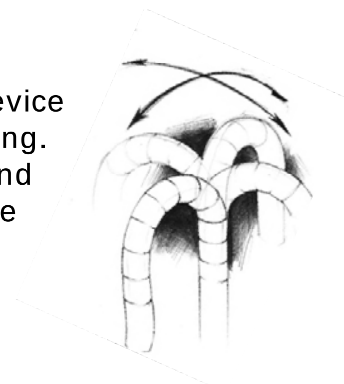
Deflectable catheters feature a tip that can be pulled into a defined curve. This is achieved by using a wire connected to a pull or anchor ring near the tip. The tip returns to its original shape through natural springback. Almost all deflectable catheters will have a degree of steerability. These devices are useful when making highly angulated turns in distal anatomy or to control exact positioning of the catheter tip. Examples include guiding catheters, implant delivery systems or EP mapping and ablation catheters.

Bi-directional catheters



Feature a tip that can be pulled in two opposing directions. This is achieved by using two pull wires connected to a distal pull ring. These devices are particularly useful for controlled movement and placement of the distal tip as they can be steered forwards and backwards. Typical examples include EP Mapping and ablation catheters and implant delivery systems.

4-way deflectable catheters

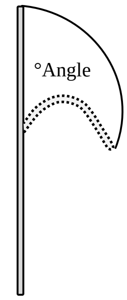


These devices can be pulled in 4 directions using a device handle. They require four wires connected to a distal pull ring. The most common 4-way deflectable devices are ultrasound imaging systems, such as ICE catheters. These can be manipulated to access multiple chambers of the heart and also view images from different angles.

Omnidirectional catheters

These are 4-way deflectable catheters remotely controlled via a robotic device to allow tip orientation in any direction. Steering is achieved by manipulating one or more pull wires simultaneously. Robotic catheters can be used for a variety of applications and provide the physician with greater control and less exposure to radiation.

Terminology – Curve Types



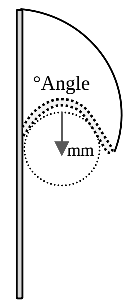
Curve Angles

Curves are usually measured in two ways.

1. As an angle of movement relative to its straight axis i.e. the bend angle.

OR

2. The bend angle relative to its bend radius*. This considers the angle of movement relative to the length of the deflectable section of the catheter (e.g. a catheter tip that can move 180 degrees within one inch).



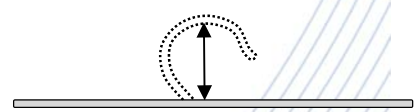
*Bend radius

This is based on the inside curvature of the catheter. It indicates the minimum radius one can bend a catheter or sheath without kinking it.

Most curve angles range between 45 and 180 degrees depending on the application, but can be up to 270 or in some instances 360 degrees.

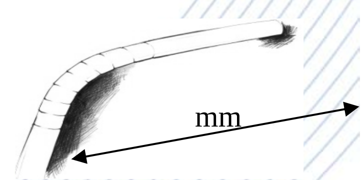
Curve Diameter

This indicates the furthest distance the catheter moves from its straight axis as is it is being deflected. The curve diameter will not always remain constant during deflection and it does not necessarily indicate the location of the catheter tip.



Reach

Reach measures the displacement of the tip from its central or straight axis. (For example when the tip is deflected 90 degrees its reach is 50mm). Maximum reach is the furthest the tip can be displaced from it straight axis.



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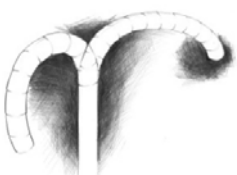
Small, Medium and Large curls
This describes the length of the deflectable section of the catheter relative to its curve diameter.

Small, Medium and Large sweep
This describes the length of the deflectable section of the catheter relative to its reach.

Symmetrical Curves
Used when describing bi-directional catheters. It indicates that identical curves are created when the catheter is deflected in one direction and then in the opposite direction.



Asymmetrical Curves
Asymmetrical curves indicate that two different curves can be produced using the same bi-directional catheter. In other words when deflected in one direction it creates a certain size of curve and when deflected in the opposite direction the shape of the curve changes.

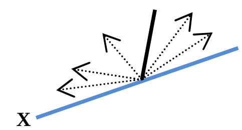
Loop catheter
Using nitinol the catheter tip forms a loop shape as it extends through a guiding sheath or delivery catheter. The guiding sheath or delivery catheter can in turn be deflectable or bi-directional. This is used as an EP diagnostic or mapping catheter.

Multi-curves or Compound curves
In some instances catheters can have two deflection points along the length of a catheter. This allows the catheter to be deflected for example into an S shape. It is achieved using two pull rings placed at different locations on the distal end of the catheter, with two to four wires attached to them.

Terminology – Curve Dimensions

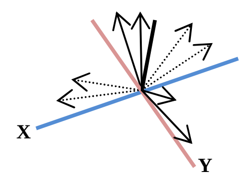
Single plane deflection / curves

This describes the movement of most bi-directional catheters. It indicates that the catheter deflects along an X axis i.e. in one direction only or side to side.



Bi-plane deflection / curves

In this case the catheter tip deflects along an X and Y axis. In other words it turns side to side and forwards or backwards i.e. a 4-way deflectable catheter. (It is sometimes used to describe 'out of plane' curves – see below)

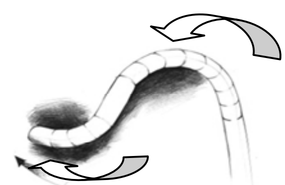


On Plane Deflection

"On-Plane" indicates that a bi-directional catheter deflects in opposing directions along the same axis i.e. single plane deflection.

Off Plane or Out of Plane

This indicates that the catheter curves off its normal X axis and has lateral movement during deflection.



Catheter Shaft Design Insights

The design of the catheter shaft is a significant factor in determining the formation of curves, angles of deflection and levels of steerability. The choice of material determines the level of pushability, torque and flexibility and it can be manipulated along the length of the catheter through a variety of means to achieve the desired results.

- Braided shafts can be adapted by changing the number of braid wires, the pique count or (PPI) pique per inch. The design can be changed along the catheter shaft, integrating multiple transition zones to achieve different stiffness characteristics. Braids can also be fibre reinforced to improve distal torque.

- Hypotubes can be laser cut to provide varying levels of flexibility as well as a defined bend radius. Similarly the laser cut design can vary along the length of the device to achieve different performance characteristics.

- Coils offer specific properties that can be adapted to achieve desired pushability and flexibility. The nature of their design means they have limited torque strength.

- All of the above can be used independently or in combination to deliver desired results. For example combining a braided proximal section with a coil or hypotube distal section.

The choice of material used in the outer and inner sheaths of the catheter and changing the durometer of this material through a series of transition zones will also impact catheter performance.