# Analysis of NMED reports for Novoste Intravascular Treatment Systems

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# System Description

- Novoste Beta-Cath and Beta-Rail Systems
  - Hand held afterloading device hydraulically propels train 12-16 Sr-90 pellets from device to tip of treatment catheter
- Beta-Cath system: introduced 1998
  - 5 F (1.6 mm OD) triple lumen catheter
  - Still marketed
- Beta-Rail system: introduced late 2002?
  - 3.5 F (1.1 mm OD) double lumen catheter
  - Engineering improvements address many types of NMED incidents

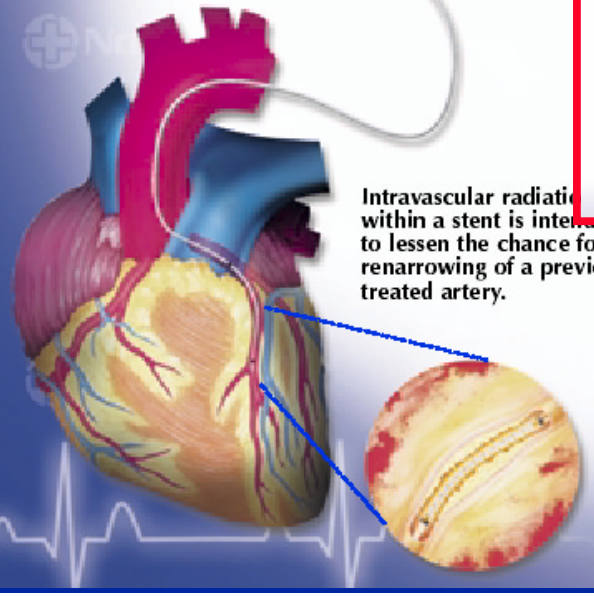
# The Novoste™ Beta-Cath™ 5F System

***SIMPLE SOLUTIONS TO COMPLEX INTERVENTIONS™***


## Radiation Source Train


### Catalog numbers for ordering:

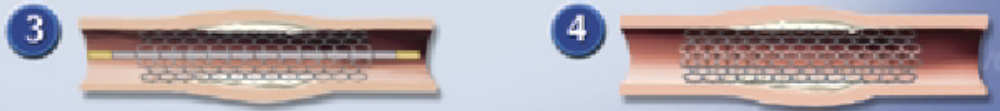
| | |
|---|---|
| BCK-0160 | β-Cath™ Delivery Catheter - 60 mm |
| TDA-0060 | Transfer Device - 60 mm Active Device |



Intravascular radiati… within a stent is inte… to lessen the chance for renarrowing of a previously treated artery.

…in-stent restenosis.

…inside stented artery.




*Radiation Source Train placed at treatment site for < 5 minutes.*

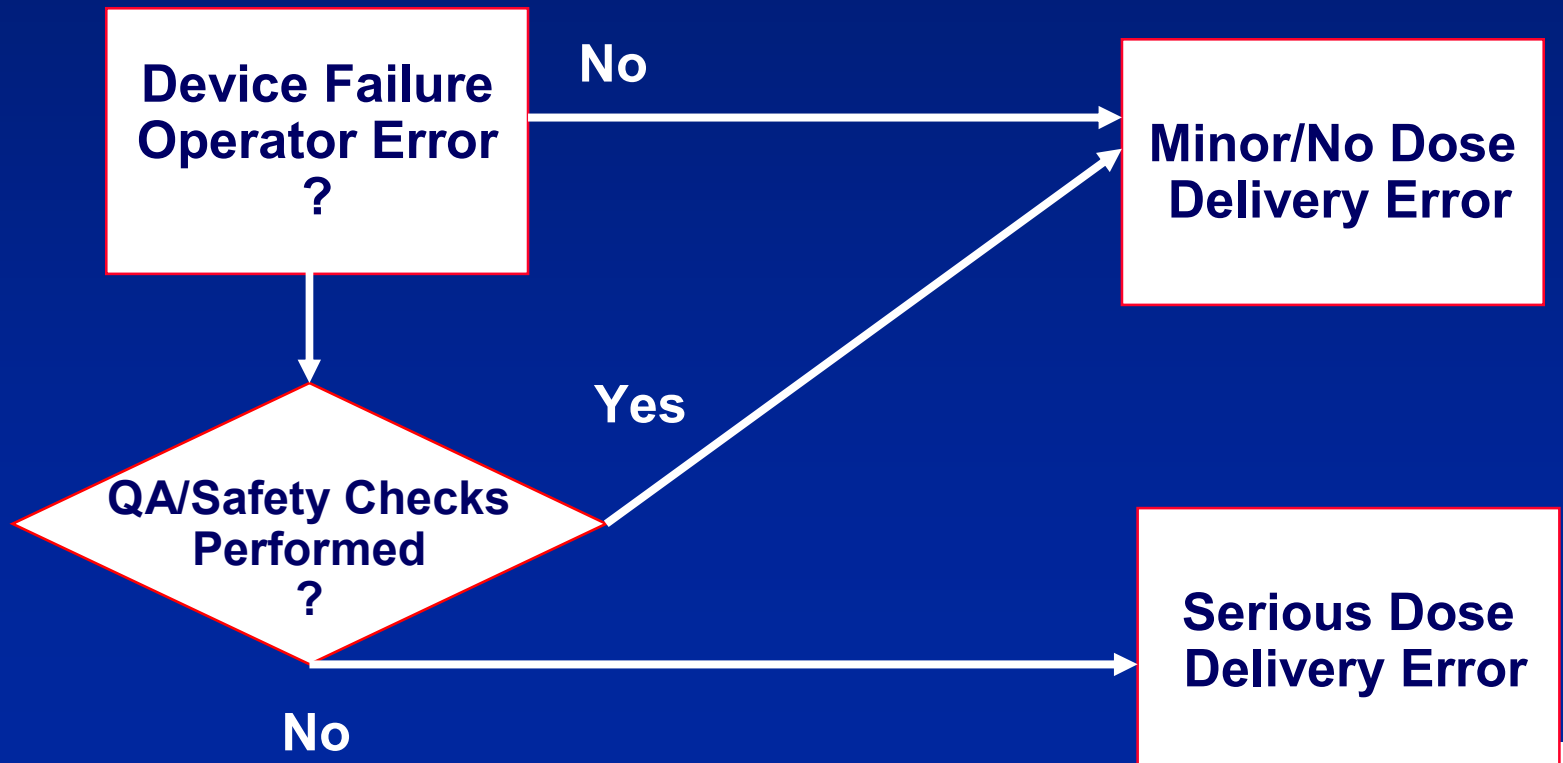
*Artery post balloon angioplasty and Vascular Brachytherapy treatment.*

# Novoste System Limitations

- Positive pressure must be exerted via syringe for sources to remain fixed in either treatment position or in retracted position
  - Failure: sources will move under influence of gravity
    - » 5F sources and markers can separate
- In contrast to cable-driven source
  - No automated measurement of source position
    - » Operator MUST verify source location fluoroscopically and have reasonable eye-hand coordination
  - OD source $\approx$ ID catheter $\Rightarrow$ Mobility sensitive to catheter deformation

# Williamson's event analysis model

- Primary Cause: Device failure or initial operator error that leads to dose error
- Secondary Cause: Omission of QA check that would have caught primary error



# Major Types of Primary Causes

- Failure of sources to reach treatment position
  - Loss of positive pressure
    - » User errors: fumbling with second syringe etc
    - » Leaking seals: design problem
    - » O-ring fragments, screws, etc., in hydraulic system
  - Catheter kinking/crimping
    - » Touhy-Bourst valve too tight
    - » Catheter (especially 3.5 F) damaged during shipping, unpacking, or insertion
    - » Underlying causes: T-B valve inadequacy + excessively fragile catheters + rough handling

# Example:  O-ring damage

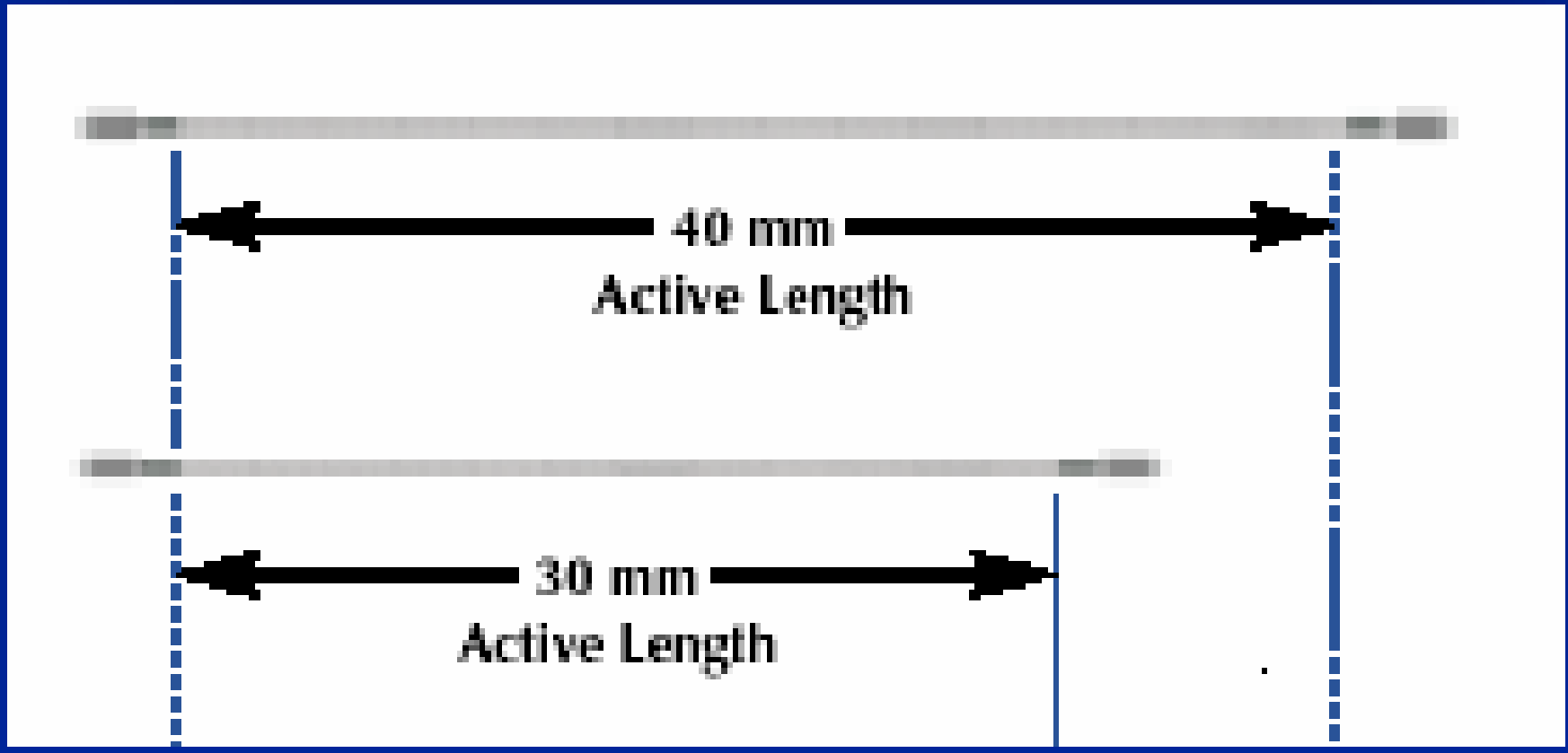
# Major Types of Primary Causes

- Source retraction failure
  - Positive pressure loss
  - Kinking
- Incorrect treatment calculation
  - Vendor calibration error
  - Stop watch incorrectly set
- Loss of source train integrity (seeds drift apart)
  - Positive pressure loss
  - Kinking

# Major types of 'Errors' and their Primary/Secondary Causes

- Large dose to wrong site
  - Kinking (P) & no fluoro localization (S)
  - On retraction {Kinking (P) OR Pressure loss (P)} & untimely emergency response
  - Pressure loss/source drift/separation (P) & no fluoro localization (S)
- Over or underdose to treatment site
  - Initial calc/cal error (P) + inadequate check (S)
  - Untimely retraction due to {Kinking (P) OR Pressure loss (P)} & untimely emergency response

# Fluoroscopic Localization



# Major types of 'Errors' and their Primary/Secondary Causes

- Loss of source control upon retraction
  - {indicator light OK & source drift} (P) + failure to visualize sources before shutting gate & disconnecting catheter (S)
  - Sources jam in gate (P) & disconnecting catheter (S)

# Ideal QA Program

- Verify calibration/labeling of all sources
- Double check each treatment time calculation and timer setting
- Equipment checks
  - Prior to insertion, test run with treatment catheter and source RAL (Test for leaking, damaged catheter, and malfunctioning RAL)
  - After catheter insertion: perform test run with dummy RAL (Test for fluoro localizability and catheter damage during insertion)

# Ideal QA Program

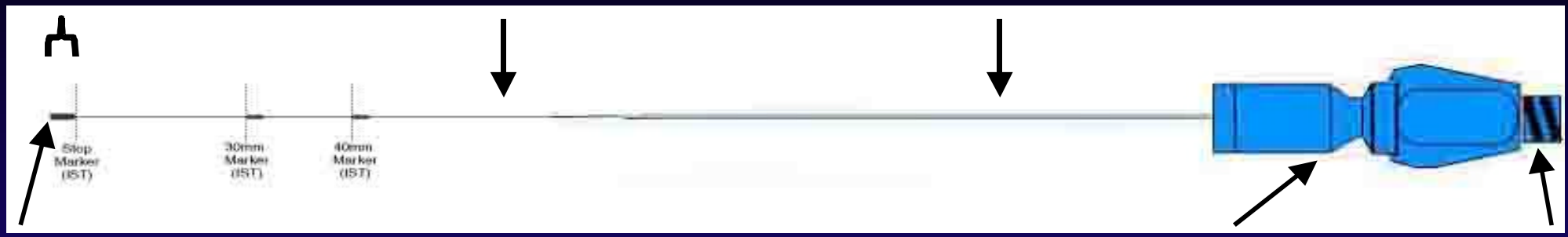
- During treatment
  - Initial fluoroscopic localization is ESSENTIAL!
  - Verify source positioning every 30 sec.
  - Ensure positive pressure maintained + extra syringe connected
  - Use T-B protector sleeve if possible
- During/After retraction
  - Maintain positive pressure until gate closed
  - Visually count sources before closing gate
  - Don’t disconnect catheter if sources don’t return
  - Survey with thin window instrument

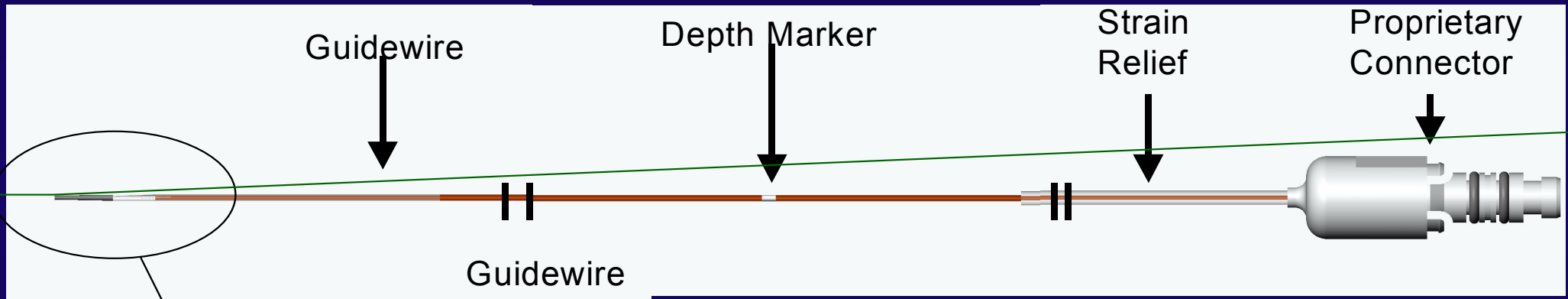
# Recent "Beta-Rail" improvements

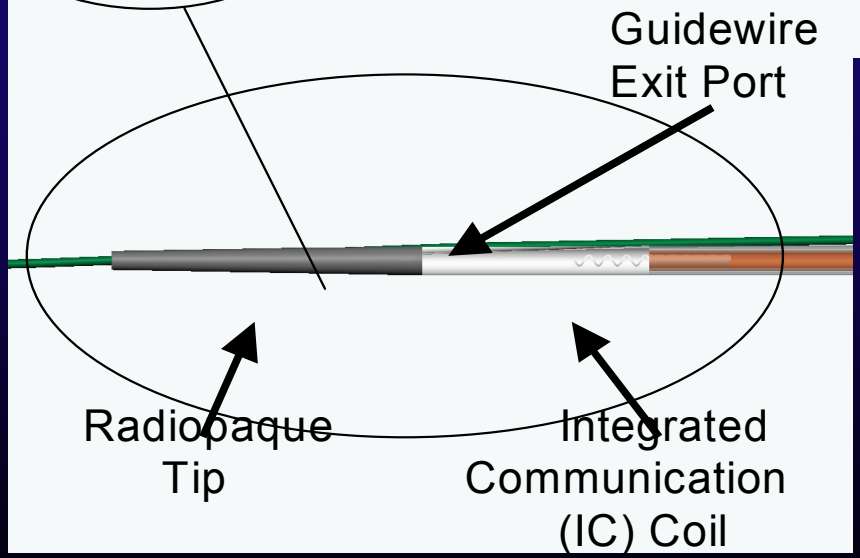
- 3.5 f catheter inserted into patient with "dummy source train" in place
  - Perhaps reduces kinks
  - Permits radiographic confirmation before Sr-90 ejected
- Sr-90 pellets encapsulated in steel spring
  - Can't separate or fool source retraction detector
- Plumbing improved: fewer leaks
- Remaining primary causes
  - Catheter deformation by T-B valve
  - Dummy source train prevents on-site testing of catheter
  - Catheter kinking??

Thin flexible distal wire

Stiffer pushable proximal wire




# β-Rail™ 3.5 F Delivery Catheter

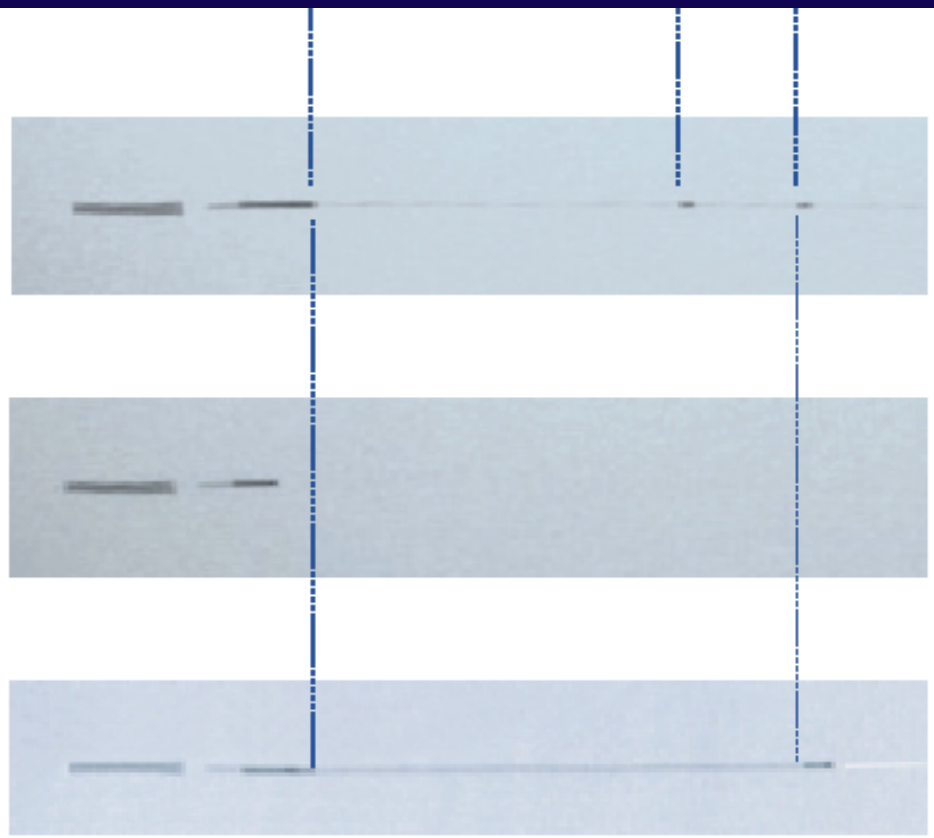
# 3.5F Beta-Cath System
# Fluoroscopy Images

## Fluoroscopic Images

*Catheter with Preloaded IST*

*Catheter Only*
*(IST removed)*

*Catheter with 40 mm JRST in Treatment Position*



# Conclusions

- Beta-Cath has ≈10-fold higher reportable event rate ($10^{-3}$) than other byproduct modalities reflecting higher rate of primary failures
- Most primary failures can be detected by meticulous technique, adequate QA and training
  - Users must adapt their implementation and QA programs to potential error pathways
  - Successful management of primary failures will result in small, clinically insignificant dose errors
- Design improvements to the 3.5 F system may reduce primary failure rate significantly