All EP Catheters Should be Reused

Raja Selvaraj

Jawaharlal Institute of Postgraduate Medical Education and Research
India

(More Extensive) Reuse of Catheters – Time Ripe to Revisit ?


SINGLE USE ONLY

- Tested for one use only

- Tested for more than one use and found unsafe

Old wine in a ~~new~~ old bottle

Reprocessed by

stryker®

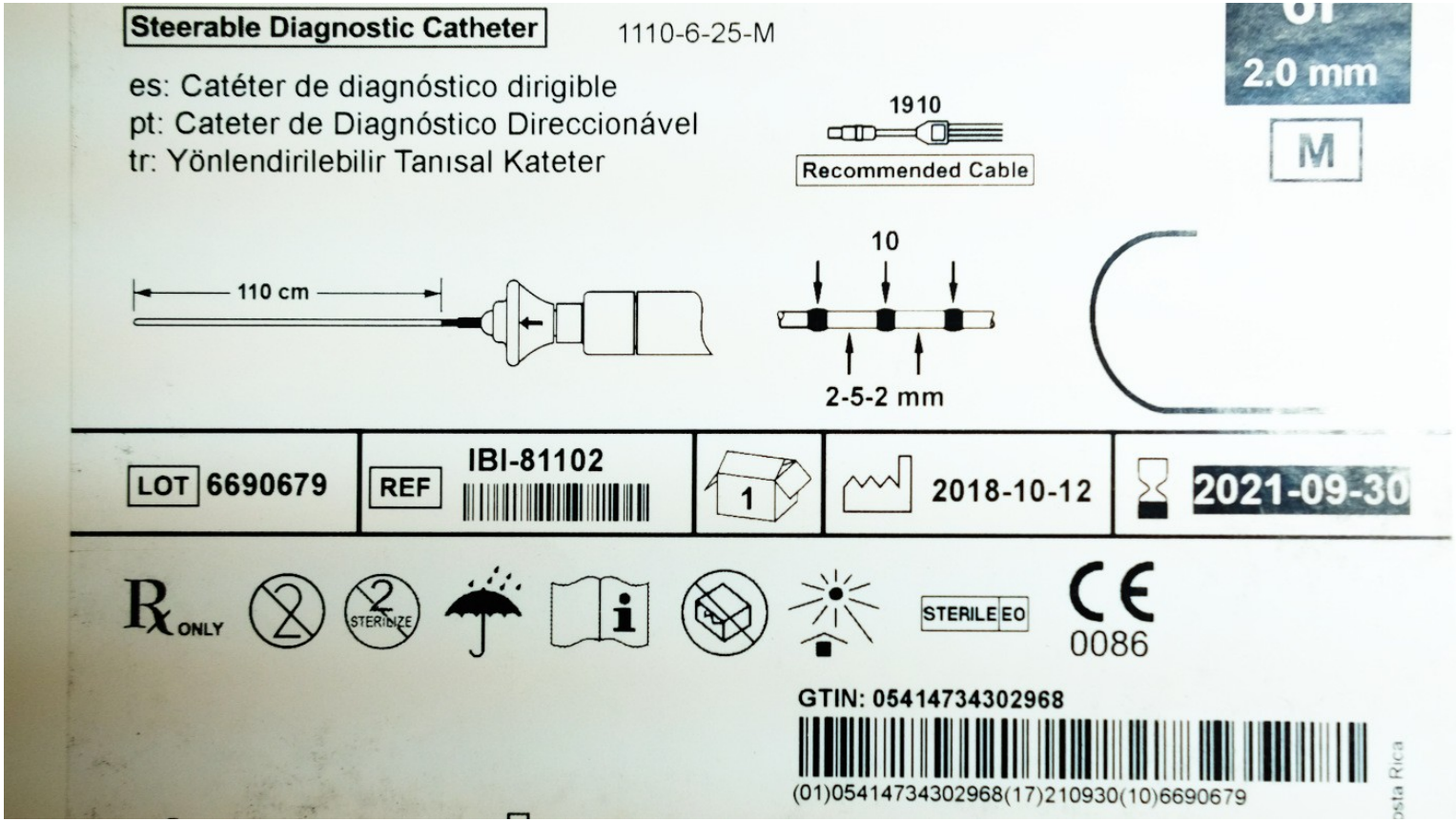
Sustainability Solutions

Instructions for Use
Reprocessed 2515 NAV/2515 NAV eco Variable and LASSO® NAV eco
Electrophysiology Catheters

Reprocessed Device for Single Use

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

- STERILE


Steerable Diagnostic Catheter
1110-6-25-M
es: Catéter de diagnóstico dirigible
pt: Cateter de Diagnóstico Direccionável
tr: Yönlendirilebilir Tanısal Kateter
1910
Recommended Cable
2.0 mm
M
110 cm
10
2-5-2 mm
LOT 6690679
REF IBI-81102
1
2018-10-12
2021-09-30
Rx ONLY
STERILIZE
STERILE EO
CE
0086
GTIN: 05414734302968
(01)05414734302968(17)210930(10)6690679

Outline of this talk

- Can we do it ? (Safe ?)
- Should we do it ? - (Reasons ?)
- Are we doing it ? - (Current practice)
- Are we allowed to do it ? - (Legal issues)
- How should we do it ? - (The way forward)

Safety concerns

- Transmission of infections due to contamination
- Toxic reactions to residue after sterilization
- Mechanical and structural integrity
- Functional efficiency

No risk of infection

- No residual pathogens after sterilization(1)
- Surveillance cultures and biological indicators negative (2)
- No increase in skin infections or incidence of bacteremia (3)

1) E. Aton et al. Safety of reusing cardiac electrophysiology catheters. AJC 1994;74 :1173-1175
2) Dunnigan A, Roberts C, McNamara M, et al. Success of re-use of cardiac electrode catheters. Am J Cardiol 1987;60:807–10.
3) O'DONOGHUE, S., & PLATIA, E. V. (1988). Reuse of Pacing Catheters: A Survey of Safety and Efficacy. Pacing and Clinical Electrophysiology, 11(9), 1279–1280.

Toxic residues

- Residual ETO may exceed recommended amounts (1)
- A 14 day waiting period sufficient to prevent this (2)
- Hydrogen peroxide plasma sterilisation - Effective, no significant residue (3)

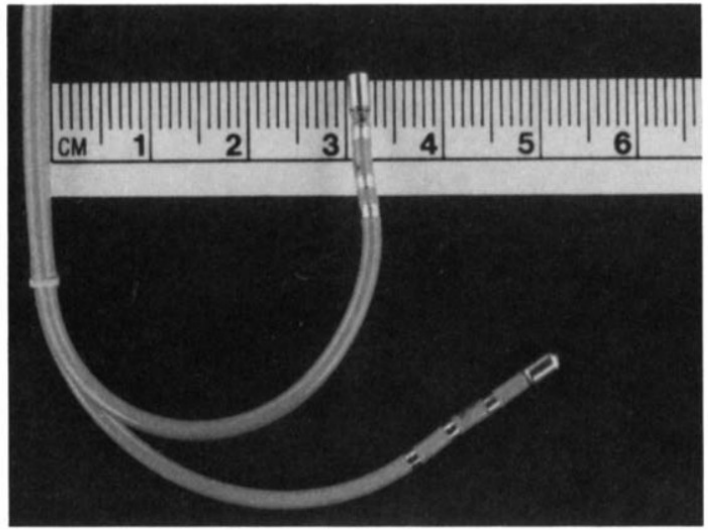
1. E. Aton et al. Safety of reusing cardiac electrophysiology catheters. AJC 1994;74 :1173-1175
2. Ferrell M et al. Ethylene oxide on electrophysiology catheters following resterilization: implications for catheter reuse. AJC. 1997;80(12):1558–1561.
3. Murali N. Bathina et al. Safety and efficacy of hydrogen peroxide plasma sterilization for repeated use of electrophysiology catheters. JACC 1998 32(5):1384-1388

Mechanical and Structural Integrity

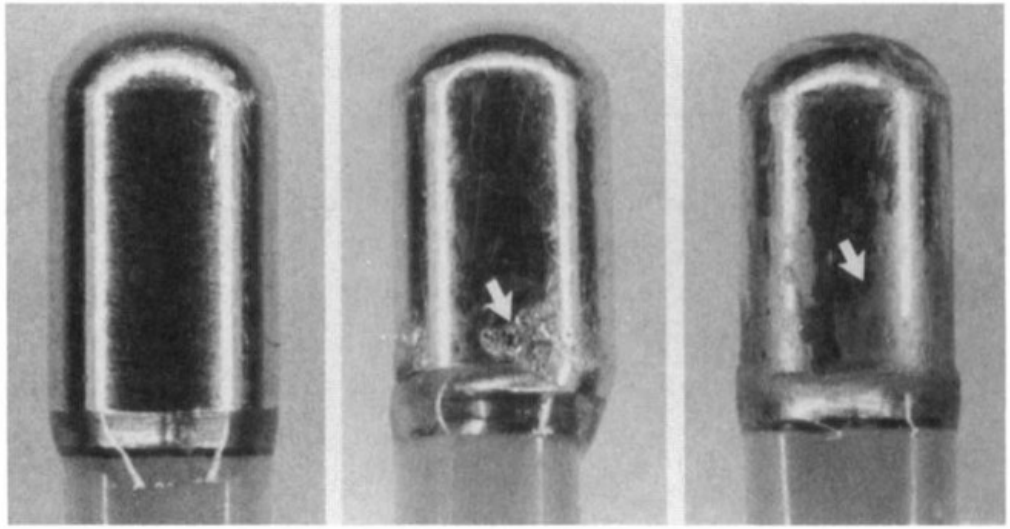
- No component failure detected by visual inspection and x-ray in 12 diagnostic catheters after reuse (1)
- More extensive prospective evaluation (2)
  - Tip electrode glue separation after 43 ± 4.3 uses
  - Loss of deflection - 5 ± 3.3 uses
  - Electrical discontinuity between handle and electrode - 10 ± 3.7 uses

1. E. Aton et al. Safety of reusing cardiac electrophysiology catheters. AJC 1994;74 :1173-1175
2. Avitall et al. Repeated use of ablation catheters: A prospective study. JACC 1993 22(5) 1367-1372.

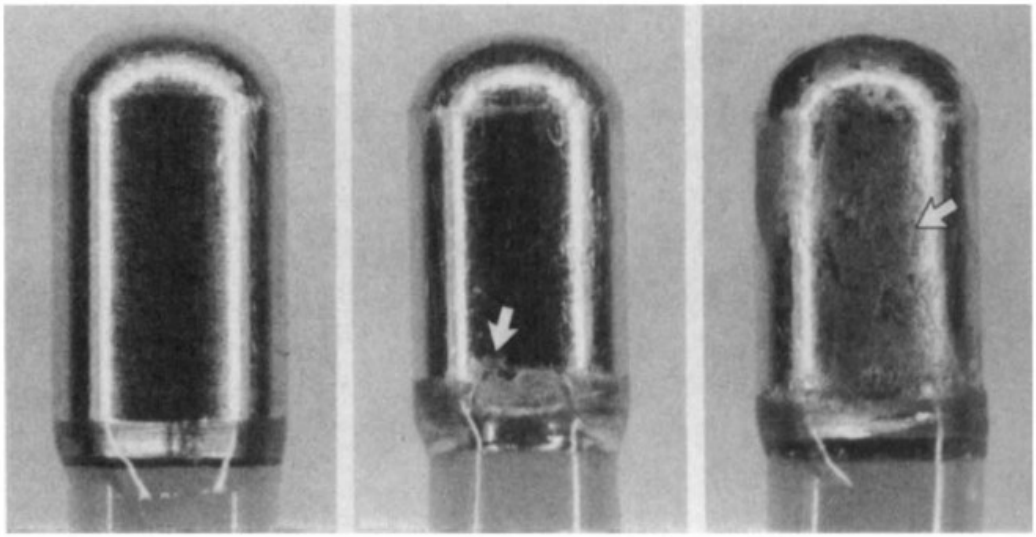
Catheter deflection



Tip damage - Pitting



Tip damage – Glue separation and crust



Functional integrity

- 58 new catheters vs 165 catheters reused 5 times
- Different manufacturers
- Electrode continuity, isolation, leakage current
- Shaft torque force, shaft stiffness, tip buckling force
- No significant difference between new and used, all within acceptable limits

Lester, B.R., Alexander, A.A., Miller, K. et al. J Interv Card Electrophysiol (2006) 17: 77.

Functional integrity

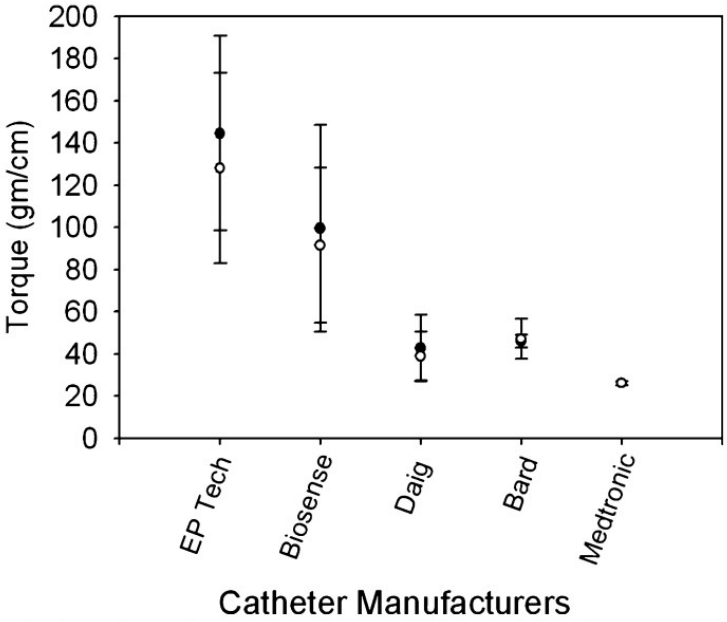


Fig. 2 Peak resultant torque for new (*filled circles*) and reprocessed (*open circles*) EP catheters. See Table 1 for the number of each new and reprocessed catheter used

Lester, B.R., Alexander, A.A., Miller, K. et al.
J Interv Card Electrophysiol (2006) 17: 77.

United States General Accounting Office

GAO

Report to Congressional Requesters

June 2000

SINGLE-USE MEDICAL DEVICES

Little Available Evidence of Harm From Reuse, but Oversight Warranted

Potential cost savings

- 150,000 USD saved per year in US by reprocessing EP catheters
- Could save upto 1.8 billion USD

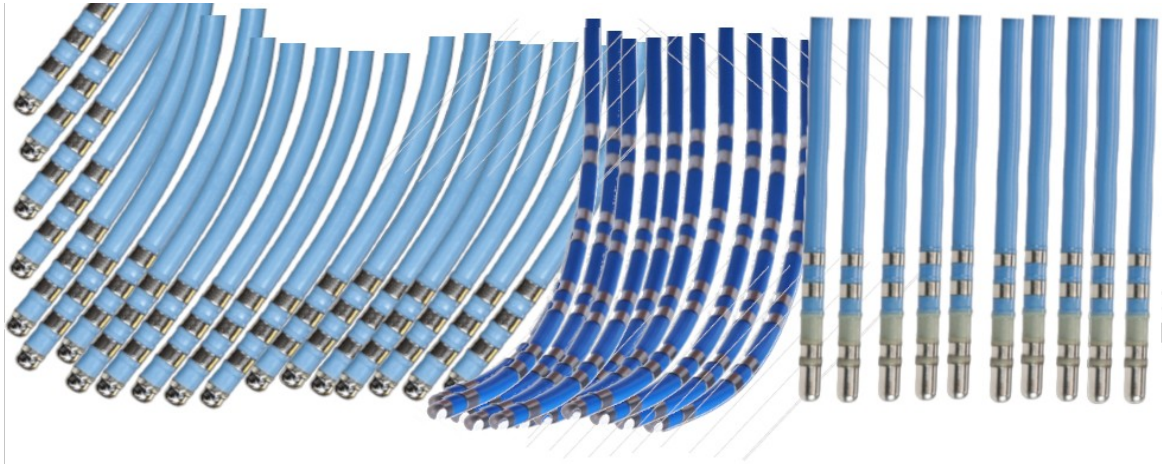
Landro L. Hospitals reuse medical devices to lower costs. Wall Street J. 2008; (March(19)) http://online.wsj.com/article/SB120588469924246975.html.

Beyond cost effectiveness

- “Green” EP
- Reduces waste produced from hospitals
- Environment friendly

Savings – 10 SVT ablations

- 88% less mass
- 78% less cost



10 procedures
Rs. 7,29,000

10 procedures
Rs. 1,62,720

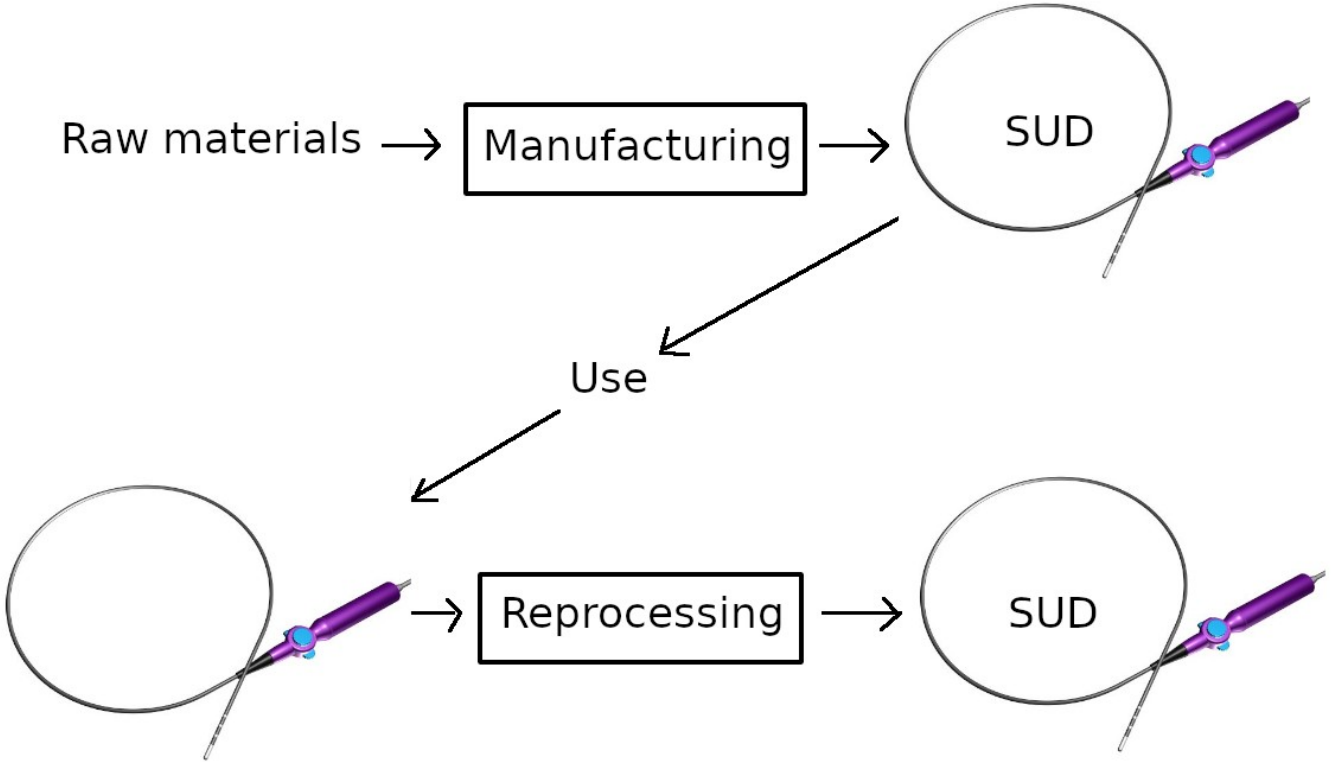
Current practice

- India / Asia
  - Extensive reuse
  - In hospital
  - Unregulated
- United States
  - Regulated by FDA
  - Third party reprocessors
  - Limited reuse
- Europe
  - Not permitted (UK, France)
  - Legal (Germany)

Legal framework (US)

- Medical Device User Fee and Modernization Act (2002)
  - Reprocessed devices subject to premarket review similar to new devices
  - Stringent regulation of reprocessors
  - Validation data on sterility and functional performance
  - Device tracking and reporting

Reprocessing is Remanufacturing !



Local challenges

- Reprocessing not covered by legal framework
- Ambiguous directions from Govt / Insurers
- In hospital reprocessing
  - No set protocol / validation / quality assurance
  - Unlimited reuse
- Unclear how to charge

The way forward

- Third party reprocessors
  - Validated protocols / Quality assurance
  - Liability
  - Government oversight (US, Canada, Japan, EU)
  - Limited reuse – To be determined by reprocessor

The way forward - Protocol

- Washing incl Enzymatic cleaning agent
- Discard if blood stains
- Disinfectant for 4 hours, Clean and dry
- Inspection and testing
- Double layer packing
- ETO, Aerate for 24 hours
- Label with date of sterilization and number of uses

Kapoor et al. Guidance on reuse of cardio-vascular catheters and devices in India: A consensus document. Indian Heart Journal 69 (2017) 357–363

The way forward

- Billing for reused catheters
  - Shared cost
  - Bill only for reprocessing cost
- Patient information
  - Consent
  - Option to opt out

In Summary

- Data for safety of reprocessed catheters
- Resistance based more on emotive issues rather than scientific evidence
- Based on absence of harm and economic and environmental gains, reprocessing is the ethical approach
- Should be done using validated protocols