

Medical devices: Pros and Cons of remanufactured goods

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Disclosure

- No relevant financial interests

Definition

- **Refurbished** : repaired, cleaned and updated to relevant safety standards. Take it back to the original state and was placed on the market as a new item. It retains its conformity and CE marking.
- **Remanufactured** : repaired and updated take the scope and state of the device beyond its original position i.e. it is 'better' than a new. Becomes different device and must reapply for conformity and for a CE marking.
- Same meaning in USA, different in Europe
- This presentation uses “refurbished”.

Company

- Refurbishment by OEM :
 - i.e. Imaging systems by Siemens, GE, Philips
- Steps: selection- de-installation-refurbishment- reinstallation- warranty

Company

- Refurbishment by a third party (refurbish or sell)
- Warranty : range 30 days – 1 year
- Voluntary, no industry standards exist for this work

Trends

- Rapid pace of advancing technology in medical devices esp. imaging technology
- Shortening interval between buying a superior system
- Greater number of devices returned to OEM or the 3rd party
- Different business model : service provider (irrespective whether new or refurbished) , lowest possible price

Barriers

- Hospitals seek for the most advanced system, 'future-proofing' equipment.
- To attract new staffs, research opportunities, care receivers.
- Pre-conception: substandard, minimal standard but not the highest capability
- Others: compromised function, incomplete decontamination & re-sterilization, lack of retesting

India Orders Panel To Restrict Import Of Refurbished Radiology Devices

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Executive Summary

The Indian government has issued orders to appoint an inter-ministerial committee to restrict the import of refurbished radiology devices and to examine whether to stop such imports, the approval requirements that are in place for such products, concerns around patient safety and the barriers faced by the domestic industry.

India Orders Panel To Restrict Import Of Refurbished Radiology Devices

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Executive Summary

Local manufacturers say the restrictions will address safety and competitive concerns. But a key importer of refurbished imaging devices says the action is all about protecting local industry.

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Urology. 2014 Jul;84(1):42-5. doi: 10.1016/j.urology.2014.01.022. Epub 2014 May 14.

Prospective evaluation of refurbished flexible ureteroscope durability seen in a large public tertiary care center with multiple surgeons.

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Abstract

OBJECTIVE: To evaluate the durability and cost of maintenance for outsourced, refurbished flexible ureteroscopes.

MATERIALS AND METHODS: Ureteroscope usage and repair were prospectively recorded over a 365-day period at a large 836-bed public hospital. Cases were performed by 14 different urologists using either refurbished DUR-8 or DUR-8 Elite model ureteroscopes. Retrograde cases involving calculi, urothelial carcinoma, stricture, and diagnostic evaluations were included. Ureteroscope repairs were performed by a single outsourced repair vendor, not the original manufacturer.

RESULTS: A total of 501 ureteroscopic cases involving 550 ureteroscope usages were performed over a 365-day period. Semirigid ureteroscopes were used for 281 (56.1%) cases and refurbished flexible ureteroscopes for 220 (43.9%). The reason for the ureteroscopy was calculi in 386 (77.0%) cases, urothelial carcinoma in 32 (6.4%), stricture in 36 (7.2%), and diagnostic in 47 (9.4%). No repairs were needed during this period for semirigid scopes. Ureteral access sheaths were used in 82 (37.7%) of the cases. A total of 32 instances of catastrophic breakage occurred. Each newly refurbished ureteroscope was used for an average of 6.9 times before incurring further damage requiring repair.

CONCLUSION: Refurbished flexible ureteroscopes that have undergone comprehensive repair are extremely fragile in the setting of multiple surgeon users in a large public hospital that uses central processing for sterilization and storage. This poor durability results in significant maintenance, repair, and administrative inconvenience that should be considered along with the purchase price.

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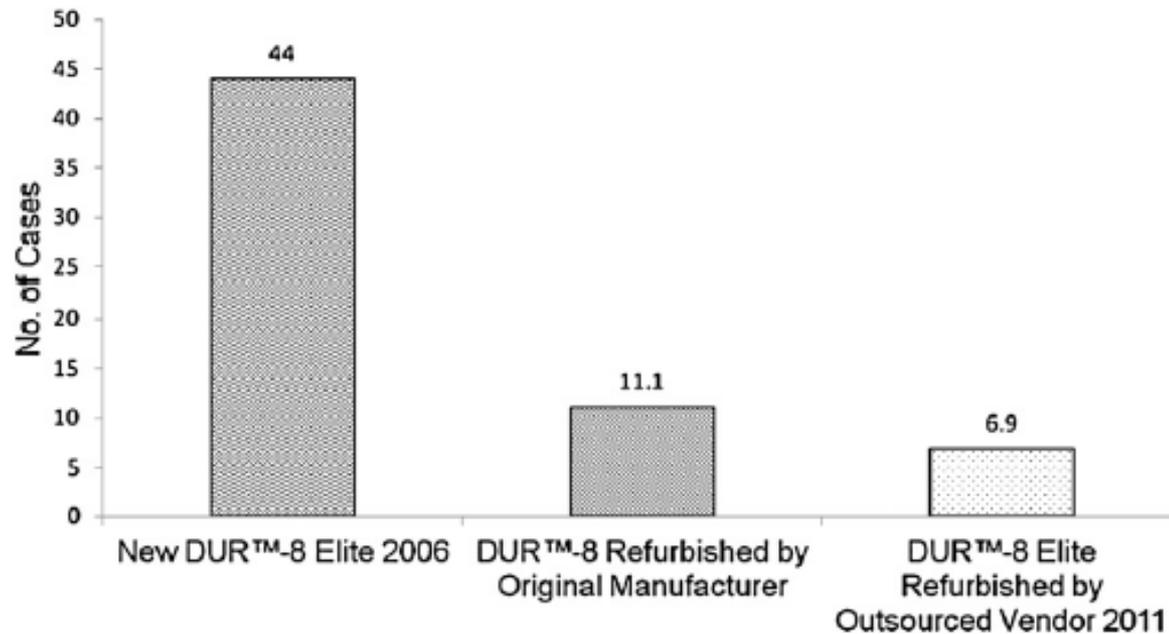


Figure 2. The new DUR-8 Elite (44 usages) and DUR-8s repaired by the original manufacturer (11.1 usages) are taken from Carey et al (J Urology 2006;176(2):607-610) and compared with the DUR-8s refurbished in this study by an outsourced vendor which showed only 6.9 usages per breakage event.

Prospective Evaluation of Refurbished Flexible Ureteroscope Durability Seen in a Large Public Tertiary Care Center With Multiple Surgeons

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CONCLUSION

Refurbished flexible ureteroscopes that have undergone comprehensive repair are extremely fragile in the setting of multiple surgeon users in a large public tertiary care center that uses central processing for sterilization and storage. The high frequency of damage and repair seen in this study results in significant administrative inconvenience and cost. The durability of outsourced, refurbished flexible ureteroscopes, cost of repair, and the initial purchase cost must be considered. Our study suggests that acquiring refurbished ureteroscopes from an outsourced vendor is an expensive, unreliable means to provide flexible ureteroscopes to a large, high surgical volume hospital.

Conclusion

- Administrator : financial, risk management, end of life of equipment
- Physician : need the most advanced technology, more accuracy, more clinical information & benefit, for the best patient care.
Not only standard but the highest capability
- Care receiver : the best quality of care from the top equipment at the affordable (same) cost , without risks