End Of Life (EOL) for brachytherapy devices

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End of life

What is meant about "End Of Life"?

- There are the three words that would cause panic at every cancer center
- Other title: Life expectancy, obsolete , end of support
- Manufacturer will stop marketing, selling or supporting the product
- Difference between shelf life and life expectancy (or useful life)

Origin of EOL

- Part of the manufacturer's proposed Instructions For Use(IFU)
- Definition from the Code of federal regulations, title 21, volume8, revised as of April1, 2014 (Cite: 21CFR803.3):

  "Expected life of a device means the time that a device is expected to remain functional after it is placed into use. Certain implanted devices have specified "end of life" EOL dates. Other devices are not labeled as to their respective EOL, but are expected to remain operational through activities such as maintenance, repairs, or upgrades, for an estimated period of time"

Origin of EOL

Could simply be that parts are no longer available to support the product and therefore…

End of life for brachytherapy devices

Factors that can affect the use of brachytherapy devices

- Cleaning agents
- Mechanical “wear and tear”
- Radiation damage
- Degradation due to UV light exposure
- Time (aging)
- Unexpected defect discovered in the product by the manufacturer
- Parts not available anymore

End of Life applies to software too!

Benefits and implications from EOL

- Patient (safety)
- Manufacturers (new products to sell)
- Users and support (something new to learn and support)
- Institutions (need to buy new products)
- Shift of Responsibility and Liability
- Help protect the users from possible serious problems
- Image of Brachytherapy

How is EOL determined?

- Testing of products
- Example: transfer tubes
- Tests performed under certain conditions
- Estimate of time or # cycles
- Simple method for all users: time is logical (using some assumptions)

How is the information provided to users?

- Provided with the equipment: Instructions for Use, manuals, etc..
- Provided by “urgent medical device notice” or BY FCO (Field Change Order) with a FCA (Field Corrective Action) included.

Nucletron

Life Expectancy

The life expectancy of the Leipzig Applicator Set is 3 years.

Warning

The Leipzig Applicator Set should only be used by physicians trained in brachytherapy techniques. The physician is responsible for its proper clinical use and the prescribed radiation dose. Prescribing and administering an unsuitable radiation dose may lead to clinical complications.

Important
User Notice

Check Applicators and Transfer Tubes aging, integrity and suitability

Product: microSelectron and Flexitron

Date: 19-11-2013
FCO: IUN 799701-00

Nucletron

Nucletron

Important User Notice

5 Consequences

Unintended disconnection of the transfer tube and applicator and possible failure to automatically retract the source cable from the transfer tube caused by:

- The use of damaged applicators or transfer tubes
- The use of kinked or contaminated transfer tubes
- The use of applicators and transfer tubes beyond its technical lifetime
- The use of unsuitable transfer tubes

6 Resolution

Check your Applicators and Transfer Tubes regularly and always prior to use regarding aging, integrity, cleanness and suitability and make sure to always remove unacceptable parts from clinical use:

- Replace applicators, accessories and transfer tubes beyond the specified life expectancy as stated in the user manual;
- Remove the referenced GYN Transfer tubes, produced before 2007, from clinical use;
- Inspect transfer tubes, applicators and accessories on a regular basis and always prior to each use, according to the instructions in the applicable user manual, unacceptable parts shall be removed from clinical use.
- Only use transfer tubes specified for your specific afterloader and applicator.

6.1 Life expectancy

- New reusable applicators and accessories have a 3 year life expectancy, applicators beyond the 3 year life expectancy should be replaced.
- MicroSelectron Transfer Tubes have a 2 year life expectancy, microSelectron transfer tubes beyond the 2 year life expectancy should be replaced.
- Flexitron Transfer Tubes have a 3 year life expectancy, Flexitron Transfer Tubes beyond the 3 year life expectancy should be replaced.
- For all other accessories, please refer to the applicable user manual for the life expectancy.

Customers who choose to continue clinical use of transfer tubes, applicators and accessories beyond the expected life assume responsibility and liability for all use.

6.2 Remove GYN Transfer Tubes, produced before 2007, from clinical use

Gynecological Transfer Tubes with the above listed parts numbers (111002, 111003, 111004) and revisions (00, 01, 02) shall be removed from clinical use.

Check the revision number which is engraved on the indexer connector of the transfer tube and/or check the number of ball-bearings inside the transfer tube connector:

Nucletron B.V.
Tel: +31 557 113 Fax: +31 557 208
oncosupport@nucletron.com

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Good morning Zoubir,

I need to verify that you have received the attached End of support letter for machine #xxxxxx. Can I stop by sometime this week to discuss? Please let me know when it will be most convenient to you.

Thanks

How do institutions deal with EOL?

- React when they first learn about it
- Very few have a plan of actions
- Every institution should be proactive and have one in place
- Rely on medical physicist input (Q.A.) for input
- Is the physicist assuming liability?
- What is the best way to check these applicators? No reliable method is available! Not an easy task.
- Have a Committee within institution to create a plan (physicist, risk management, legal, administration).

Is it possible to have a plan for everyone?

- At the present time: no!
- Device usage, sterilization being different
- Possibility: replacement cost for applicators imbedded in the service contract. Standard for everyone.
- Replacement based on institution's usage (detailed contract)
- Legal, based on reliable info from physics to continue the use and assume responsibility: must evaluate all risks possible.
- Plan ahead for replacement (budget)
- Act in advance: time saving, possibility of trade-in
- Others

Case example (extreme one)

- Assume Mrs. Jones was treated with a GYN applicator
- During the second application the applicator broke inside the patient
- Difficulties in retrieving the applicator and the source but successful after 10 minutes beyond Tx time
- Dose evaluated and results show a medical event occurred
- As a result there was a lawsuit

Example case

- Attorney did his homework and discovered something called EOL
- Physicist was asked to testify on this case
- Physicist was shown EOL document from manufacturer
- Document shows device at 10 years beyond EOL
- Conclusion: the device should not have been used.
- Outcome: several possibilities but all have one thing in common. Patient overdose .

Purpose of this case

- One case can make the headline
- Bad outcome for the patient
- Huge loss for the institution
- Bad reputation for the modality
- Bad reputation for the practice
- Financial consequences vs. applicator replacement
- Physicists and institutions to be proactive

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BRACHYBLAST

American Brachytherapy Society

In This Issue

End of Life Requirements for Brachytherapy Medical Devices

Quick Links

Welcome to the new monthly communication of the American Brachytherapy Society called BrachyBlast. The BrachyBlast will be somewhat informal and we welcome your feedback on issues relevant to your practice. This month's topic is regarding the the end of life requirements for brachytherapy medical devices.

Thank you,
David E. Wazer, MD
David K. Gaffney, MD, PhD
Daniel G. Petereit, MD

End of Life Requirements for Brachytherapy Medical Devices

As many of you are aware, this topic is actively being discussed and analyzed. More importantly, the method for identifying and addressing end of life (EOL) requirements for brachytherapy device is not always obvious. The ABS Physics Committee has formed a subcommittee (Wayne Butler PhD, Gilad Cohen MS, Christopher Melhus PhD, Zoubir Ouhib MS, Sujatha Pai MS, Mark Rivard PhD, Manny Subramanian PhD, and Dorin Todor PhD) to provide guidance and help physicians and physicists to address this issue. The primary purpose of this document is to inform the ABS membership about this issue. Because of its complexity, suggested solutions are forthcoming. The following is a set of questions that your institution may consider:

1) Why does the manufacturer have EOL recommendations?
2) What motivated the EOL issue?
3) Who is going to benefit from EOL recommendations?
4) Is there a model for guidance on EOL issues?
5) What happens if my institution decides not to comply with manufacturer recommendations?
6) What is the safe thing to do?

References for the topic (Special thanks to Tom Heaton)

- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm150083.htm
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/DeviceLabeling/QualitySystemRegulationLabelingRequirements/default.htm
- http://www.fda.gov/downloads/MedicalDevices/.../UCM081366.pdf
- http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/default.htm?utm_source=Members-Only%20Updates
- http://www.fda.gov/Cosmetics/Labeling/ExpirationDating/default.htm
- http://www.alticoadvisors.com/Portals/0/Device%20Packaging%20-%20Top%2010%20Mistakes%20-%20Copy.pdf
- http://elsmar.com/Forums/showthread.php?t=48880
- http://www.nejm.org/doi/full/10.1056/NEJMc060053
- http://www.medtech.org/news/global.aspx?recid=4174
- http://www.astho.org/Programs/Preparedness/Public-Health-Emergency-Law/Emergency-Use-
- Authorization-Toolkit/Federal-Shelf-Life-Extension-Program-Fact-Sheet/ http://www.btlaw.com/alert-fda-amends-proposed-rule-on-unique-medical-device-identification-november-2012/

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