

Title	Use of Controlled Low Dose Gamma Irradiation to Sterilize Allograft Tendons
	for ACL Reconstruction: Biomechanical and Clinical Perspective
Author	Brian Samsell, Mark Moore
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Purpose of	To describe key variables of irradiation and present biomechanical,
Study	clinical, and safety assessments of irradiated tendons
Sponsor	LifeNet Health authors
Objective	To provide supporting material when countering concerns regarding irradiated tendons
Key Variables	Target dose- a single reported dose should be considered the minimum amount of radiation received
	<ul> <li>Dose range- a more accurate reporting that provides the</li> </ul>
	minimum and maximum quantity of irradiation received
	Temperature of irradiation- irradiating at low temperatures (dry
	ice) can minimize free radical generation
	• Tissue treatment prior to irradiation- does the treatment involve
1	harsh chemicals or physical forces that may damage tissue?
Issues	(1) There are negative reports on irradiation. However, they are
	typically flawed and poorly understood as detailed in the article.
	(2) LifeNet Health tendons are provided to a medical device grade of
	sterility and this message should stay front and center.
	(3) Banks who claim to not irradiate, or at least not terminally irradiate,
	may still pre-irradiate. It is extremely important that the customer knows
Relevance to	what they are getting from other banks.
LNH	(1) It is important to understand that not all irradiation process are the
	same, as explained under the Irradiation Methods section.
	<ul><li>(2) LifeNet Health is able to irradiate without damaging tissue.</li><li>(3) There is support, both biomechanical and clinical for the use of</li></ul>
	irradiated tendons.
	(4) Those reports of negative clinical results with irradiated tendons are
	often flawed as detailed. The significant flaws may include undefined or
	ill-advised irradiation methods and interpretation of data.
FIELD	Use this piece as support material when facing issues regarding
DIRECTION:	irradiation. There is no reason to lead with this if irradiation has not
	been expressed as an issue. This may be used when very specific
	publications are brought up as 'evidence' against irradiation. It may be
	used to educate that not all irradiation methods are the same. It can be a
	leave behind if appropriate. Be aware that the surgeon may bring up
	publications not mentioned here. Feel free to contact the home office for
	further support.