

enovis

STAR® e+

VITAMIN E BLENDED POLYETHYLENE

TOTAL ANKLE REPLACEMENT



ONE OF A KIND

THE ONLY MOBILE BEARING ANKLE SYSTEM WITH $e+^{TM}$

STAR® Ankle is the only mobile bearing ankle system on the market with e+ poly, Vitamin E blended polyethylene, which is formulated to maintain strength and reduce long-term wear.¹

The same dimensions as the legacy implant, e+ poly provides resistance to oxidation, consistent wear rates, and stable mechanical properties even in the case of accelerated aging.



FEATURES & BENEFITS

RE-MELTING NOT REQUIRED

In the case of most highly cross-linked polyethylenes, an anneal or re-melt step occurs following cross-linking to link free radicals (created by the irradiation). Annealing or re-melting polyethylene can reduce mechanical strength properties.²

Because vitamin E neutralizes the negative effects of free radicals³, an anneal or re-melt step is rendered unnecessary. In a material yield strength test, a highly cross-linked traditional polyethylene remelted sample exhibited a **12% drop in yield strength**.¹

NATURALLY OCCURING ANTIOXIDANT

Vitamin E (a-tocopherol) is the most effective naturally occurring anti-oxidant in the human body.³



PROVEN

e+™ POLY EXPERIENCE

The STAR® e^{+m} vitamin E blended polyethylene is the same e^+ moderately cross-linked polyethylene used for years in other Enovis products.





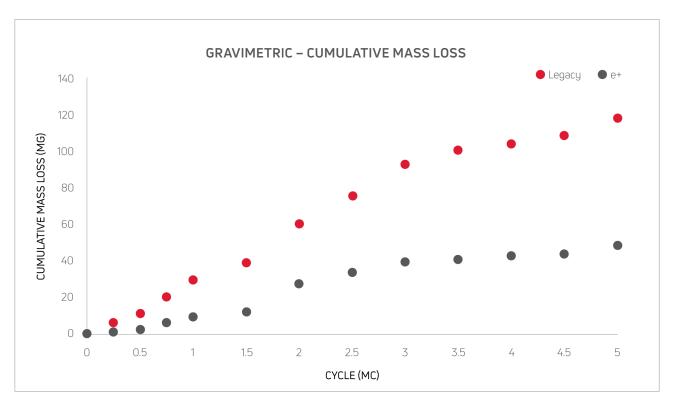






IMPROVED WEAR PERFORMANCE DUE TO INCREASED CROSSLINKING

STAR® e+™ Vitamin E blended polyethylene is a moderately crosslinked, gamma-sterilized UHMWPE with vitamin E for sliding and gliding kinematics has demonstrated a **significant reduction in oxidation and long-term wear.**¹

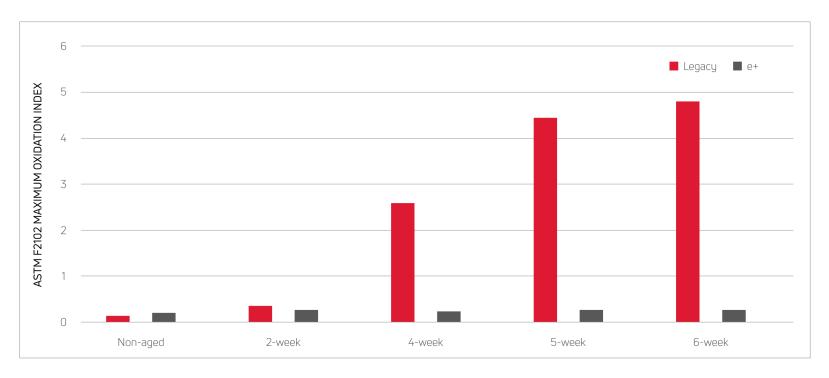


Average cumulative mass loss for STAR® Ankle UHMWPE Sliding Cores.¹

ACCELERATED AGING PERFORMANCE

IMPROVED LONG-TERM FRACTURE TOUGHNESS DUE TO OXIDATIVE RESISTANCE

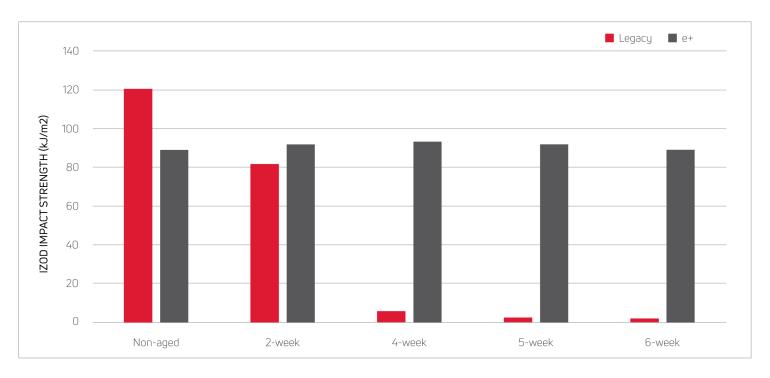
Infrared spectroscopy (FTIR) analysis showed no detectable oxidation in un-aged and intensely aged e+ samples.¹ This analysis explains why intense aging appears to have no effect on test samples.



Average Oxidation Index by material and aging time.¹

Overall, the observed fracture in the Legacy inserts appears consistent with the morphology of the fractures observed on retrievals. The limited number of cycles resulting in fracture are likely due to the aggressive nature of the test and the advanced oxidative state of the material.

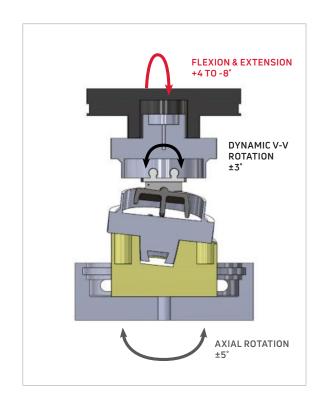
It is important to reiterate that pilot testing showed that under the same input conditions, fracture does not initiate in unoxidized material. Like non-aged conventional material, the results from the accelerated-aged e+ insert suggests the stabilized material significantly reduces the effect of oxidation and enables the inserts to reach the 3 MC runout, thus improving the expected fatigue performance of the STAR® Ankle.¹



Comparison of Legacy and e+ Izod Impact Strength across aging timepoints.¹

ANALYSIS

Testing was performed to 3.0 million cycles (MC), stopping every 0.25 MC for the first 1.0 MC and then every 0.5 MC for interval analysis.





ORDERING INFORMATION

STAR e+™ IMPLANTS

PART #	DESCRIPTION
602-03-006	6MM e+ SLIDING CORE
602-03-007	7MM e+ SLIDING CORE
602-03-008	8MM e+ SLIDING CORE
602-03-009	9MM e+ SLIDING CORE
602-03-010	10MM e+ SLIDING CORE
602-03-011	11MM e+ SLIDING CORE
602-03-012	12MM e+ SLIDING CORE
602-03-013	13MM e+ SLIDING CORE

REFERENCES

- **1.** e+ testing data on file. Bench test results not necessarily indicative of clinical performance.
- 2. S.M. Kurtz. "The UHMWPE Handbook: Ultra-high Molecular Weight Polyethylene in Total Joint Replacement". Elsevier Academic Press, 2009.
- 3. Jennings et al. The influence of femoral condular lift-off on the wear of artificial knee joints. Proc Inst Mech Eng [H]. 2007 Apr;221(3):305-14.

NOTES

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