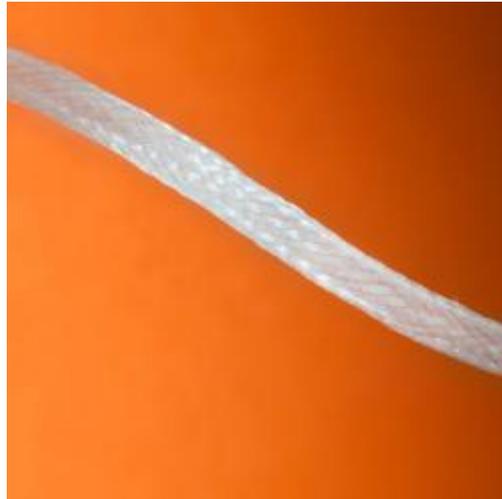


Technical specification of Scaffdex braided scaffold, CellVessel™



CellVessel™ is made of bioabsorbable multifilament (8-filaments) poly-96L/4D-lactide copolymer fiber. The polymer material is medical grade and used widely in clinical, surgical orthopedic applications since 1999. Scaffdex braided scaffold is made for research purposes, only and it should not be used in any kind of clinical settings.

Compared to more common polyglycolide (PGA) material poly-96L/4D-lactide copolymer has longer strength retention and degradation periods and stands gamma irradiation as sterilization method. When evaluated against poly-L-lactide homopolymer (PLLA), poly-96L/4D-lactide copolymer has lower crystallinity and shorter strength retention and degradation periods, however mechanical properties are equal to PLLA. Decrease of strength properties of gamma irradiated poly-96L/4D-lactide copolymer starts typically after 28 weeks (7 months) in vitro, complete absorption takes longer, even up to 76 weeks (1.5 years). Poly-96L/4D-lactide copolymer has been tested with various cell types¹ and it works especially well with fibroblasts.

Scaffdex braided CellVessel scaffolds are provided as gamma sterilized and with three widths (table 1). The shape of the cross section of CellVessel varies a little bit from complete round to oval, depending on the size. If further sterilization is needed before cell culturing we propose ethylene oxide (EtO) or ethanol rinse to avoid further decreasing of inherent viscosity and strength properties. We prefer to provide gamma sterilized scaffolds because radiation gives stable, foreseeable absorption properties of the material. The length of delivered pieces is 100 mm. Should CellVessels be cut into wanted length by the user, we recommend light heat treatment of the ends of the two bigger sizes to avoid the unloading of the structure during testing.

¹ Ruuttila, P. 2000. Material properties and tissue reactions to bioabsorbable composite orbital implant. Master of Science thesis. Tampere University of Technology, Department of Materials Engineering.

Cutting of CellVessel™ is easy with simple soldering/branding equipment with heated surgical knife tip (Figure 1). Cut surface is slightly heated and ends of filament melt together, but tubular structure is well maintained (Figure 2). Smooth plastic handle of the equipment can be wiped with disinfectants. This kind of equipment is available for example in Claes Ohlson net store / Cotech branding kit.

Table 1. CellVessel™ product selection

CellVessel™	Ref: V00001	Ref:V00002	Ref:V00003
Shape	Round	Round	Oval
Outer diameter (mm)	1.7 ± 0.2	2.4 ± 0.2	2.9 ± 0.2
Length (mm)	100 ± 2	100 ± 2	100 ± 2

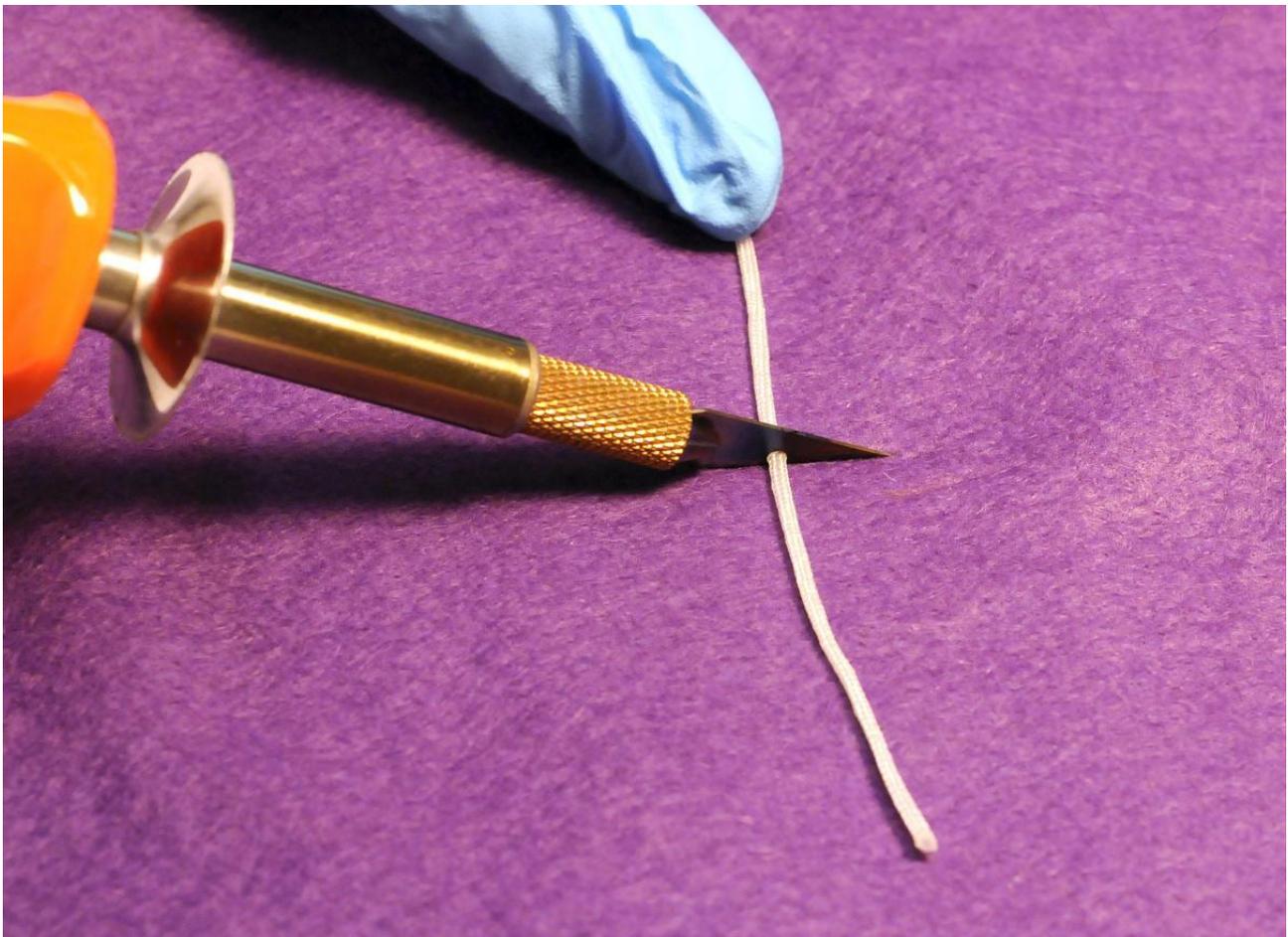


Figure 1. Cutting of CellVessel™

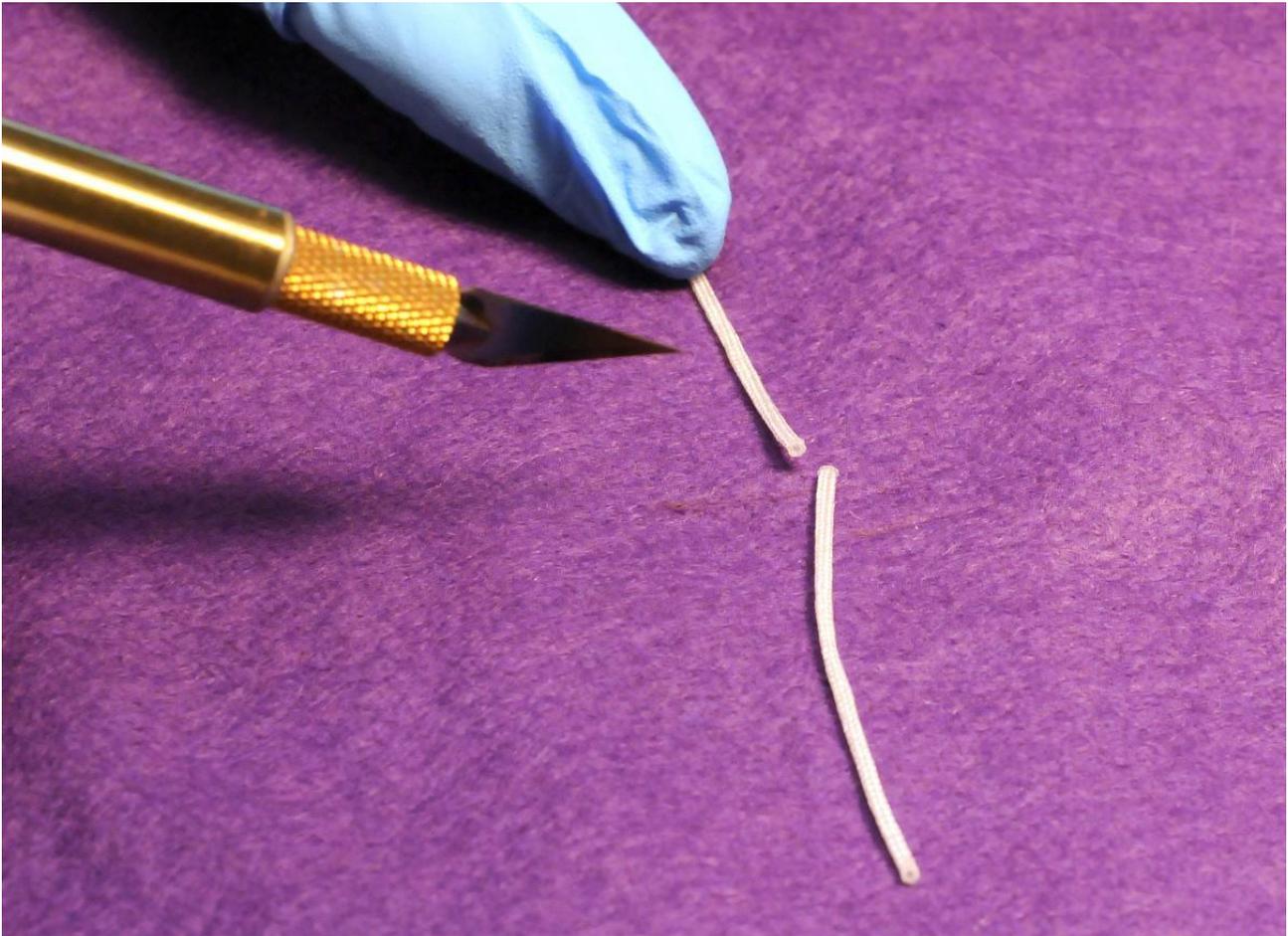


Figure 2. CellVessel™ after cutting

Diameter of single filament varies between 60-70 μm . The measured tensile force (N) of this structure is 180 - 200 N, percentage of strain 45 – 50 % and Young modulus 850 – 900 MPa. CellVessels are sold as sterile and packed one in each package.

Poly-96L/4D-lactide copolymer has been tested with various cell types and CellVessel™ is used for example in research of tissue engineered urinary tract. Further information of the tested cell types is available in literature review in Scaffdex web site

http://www.scaffdex.com/sites/default/files/literature_review_PLA_copo_964_rev1.pdf