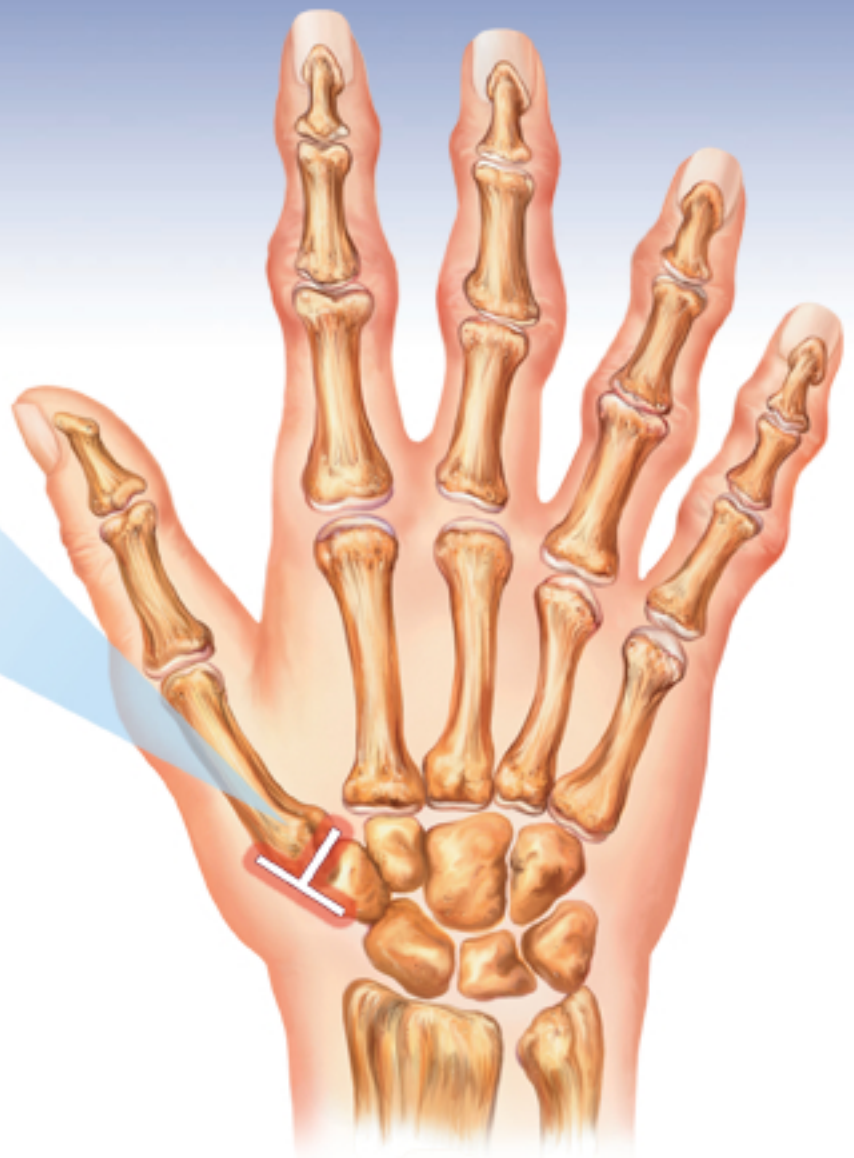


SBi

SMALL BONE INNOVATIONS

Artelon[®]
CMC Spacer *

BIOMATERIAL BRIEF



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Artelon® Biomaterial

The ARTELON biomaterial is *NOT* a new material as its chemical components can be found in products marketed worldwide. ARTELON has been shown, *in vivo* and clinically, to possess optimal biocompatibility and biomechanics for the CMC spacer. The unique patented ARTELON combines the well known chemistry and degradation products of the bioabsorbable polyester, ϵ -polycaprolactone, with known chemistry of a non-degradable poly(urethane-urea) that has been clinically utilized in vascular devices worldwide. These two components work together to provide an optimal scaffold for tissue ingrowth in the joint space and support of the CMC joint during healing.

Degradable Component: ϵ -polycaprolactone

Approximately half of ARTELON is comprised of a degradable polyester known as ϵ -polycaprolactone. This degradable polymer can be found in a number of implantable degradable devices on the worldwide market. Most notable are two monofilament absorbable sutures that contain ϵ -polycaprolactone co-polymerized with other absorbable polymers. The branded monofilament sutures are Monocryl® (Ethicon) and Caprosyn® (Tyco Healthcare). Also, a number of bioabsorbable braided sutures utilize ϵ -polycaprolactone as a coating to prevent the braided structure from dragging through soft tissue as it is used. The brands of braided absorbable sutures that utilize ϵ -polycaprolactone as a coating include Vicryl® and Panacryl® (Ethicon); and Dexon® and Polysorb® (Tyco Healthcare). All of these products are approved by the US FDA and are distributed worldwide collectively representing over \$500 million in annual sales.

Non-degradable Component: poly(urethane-urea)

The balance of the ARTELON material is comprised of a non-degradable biocompatible poly(urethane-urea). This class of polyurethane is widely used in long-term implantable devices mostly in the global cardiovascular market space. Permanent implantable devices such as artificial hearts and ventricular assist devices, pacemaker leads, long-term vascular access catheters, implantable CSF shunts and prostheses utilize these polyurethane biomaterials exclusively. A brand of raw material currently used in these various devices is known as BioSpan® (The Polymer Technology Group).