



## ARTELON PRODUCT LISTING

PRODUCT NUMBER	PRODUCT DESCRIPTION	SIZE
31050	FlexPatch	3 x 4 cm
31048	FlexPatch	4 x 6 cm
31049	FlexPatch	6 x 9 cm
31051	FlexBand	0.3 x 8 cm
31052	FlexBand	0.3 x 16 cm
31059	FlexBand	0.3 x 32 cm
31053	FlexBand	0.5 x 8 cm
31054	FlexBand	0.5 x 16 cm
31057	FlexBand	0.5 x 32 cm
31055	FlexBand	0.7 x 8 cm
31056	FlexBand	0.7 x 16 cm
31058	FlexBand	0.7 x 32 cm

## REFERENCES

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2. Data on File. 1011845A Cytotoxici
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7. Data on File. 1015733A A Histological Evaluation of the Artelon Augmented Device A
8. Peterson et al. Knee Surg Sports Traumatol Arthrosc 22:2109-2120 (201
9. Gretzer et al. J Biomater Sci Polymer Ed 17(6); 669-687 (200
10. Stenhamre et al. J Tissue Eng Regen Med 5: 578-588 (2011)
11. Gersoff WK et al. J Knee Surg. (2018) Apr 27.

For further product information or to arrange a product demonstration, please contact your local Artelon representative or call Customer Service at **800-610-3446** or email [customerservice@artelon.com](mailto:customerservice@artelon.com).



Artelon  
2252 Northwest Parkway SE  
Suite G  
Marietta, GA 30067  
Phone: 800-610-3446  
Email: [customerservice@artelon.com](mailto:customerservice@artelon.com)  
Online: [www.artelon.com](http://www.artelon.com)

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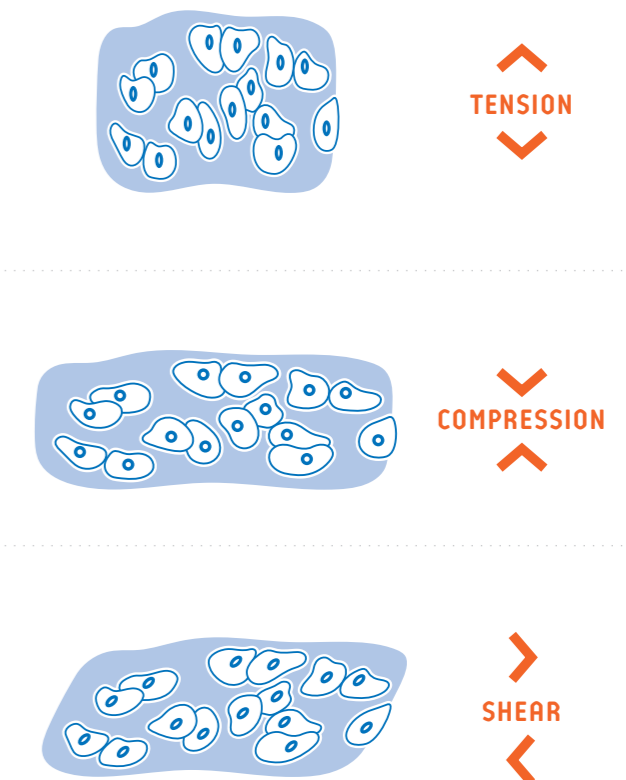


BIOLOGICALLY DYNAMIC MATRIX

## IN TENDONS AND LIGAMENTS, BIOLOGY RELIES ON PHYSIOLOGY

Biocompatibility is coexistence with living tissues or organisms without causing harm. However, for materials interacting with tendons and ligaments (T&L), 'biocompatibility' is only part of the story. These tissues require 'physiocompatibility' with biomaterials in order to coexist without altering the body's preferred paths of motion or loading profile. In fact, the origin of T&L injuries is often due to under or over loading the tissue, impairing the local T&L cells from maintaining normal tendon health and function.

The cells composing T&L tissue are highly mechano-sensitive, modifying the tissue in response to changes in T&L loads (Figure 1).<sup>1</sup> Therefore, it is paramount that augmentation promotes increased strength with unaltered stiffness to achieve protection of both the reconstruction and native motion. Without both, compromise of either the T&L tissue or joint surface is imminent.



**FIGURE 1:** T&L cells are greatly influenced by loading which directly plays a role in cellular signaling, recruitment, reproduction, and mature tissue quality

**PROVEN SOFT TISSUE COMPATIBILITY**

Artelon's Dynamic Matrix is a synthetic knitted copolymer bio-textile comprised of two well established biomaterial polymers – polycaprolactone and polyurethane urea. Extensive testing has characterized this product as safe<sup>2-8</sup> as well as less inflammatory than common biomaterials such as titanium and polystyrene.<sup>8</sup> Furthermore, long-term data has shown the Dynamic Matrix supports the regeneration, ingrowth, and conversion to host connective tissue.<sup>5,6</sup>

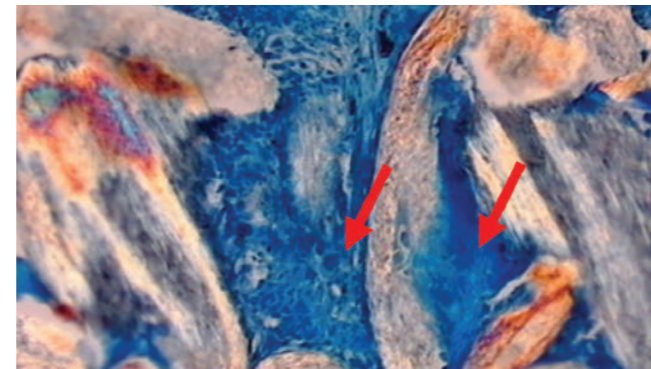
**KNOWN TISSUE REGENERATION**

Advanced engineering of these matrices allows healing tissues to be protected while mechanically engaged through motion,<sup>11</sup> resulting in stimulation, integration and be replaced by regenerated host tissue.<sup>5,6</sup> This evidence includes in-vivo animal and human studies.

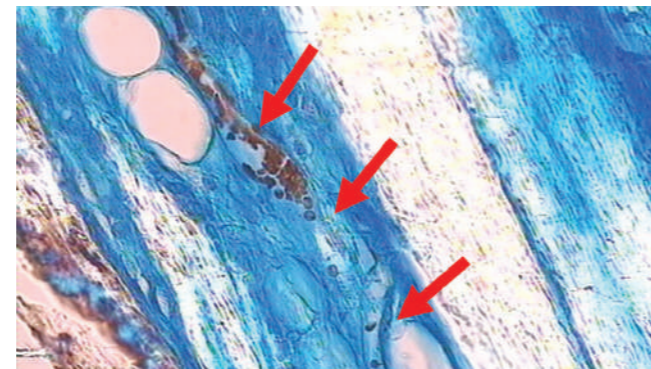
**ANIMAL EVIDENCE**

Initial rabbit studies demonstrated bone integration with cortical contact (Figure 2) and soft tissue ingrowth in ligamentous context (Figure 3). These rabbit studies included 9 New Zealand White rabbits with Artelon's Dynamic Matrix implanted intra-articularly at the knee and followed out to 18 months. A second group of 26 rabbits replaced resected ACL's with Artelon FlexBand and were followed out to 24 months. The combination of these two studies demonstrated very little tissue reaction; the regeneration of fibrous tissue, bony tissue, and vascularity into the matrix; and no observed degradation of the surrounding articular cartilage (Figures 2 & 3).

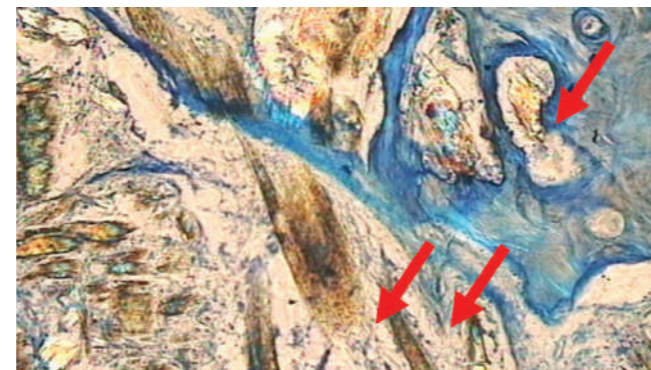
A minipig ACL model was used to further investigate the biocompatibility of Artelon's matrix out to 24 months. This study confirmed the observations in the rabbit study: 1. kinematic stability; 2. preservation of the articular cartilage; 3. no presence of synovial reaction; 4. osseous integration within the cortical passage; and 5. dense, oriented connected tissue integrated within the resorbing matrix (Figures 4 & 5).



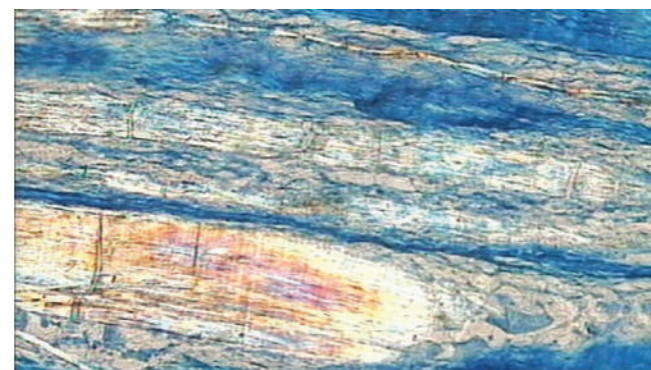
**FIGURE 2:** Htx-Van Giseon Staining of rabbit ACL at 6 months demonstrating ingrowth of bone between Artelon Dynamic Matrix fibers (see arrows).



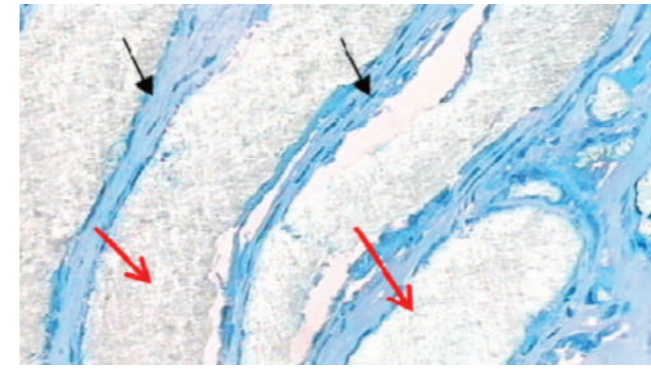
**FIGURE 3:** Rabbit ACL at 24 months demonstrating blood vessels (see arrows) in the newly formed soft tissue (blue) between remaining Artelon Dynamic Matrix fibers (white).



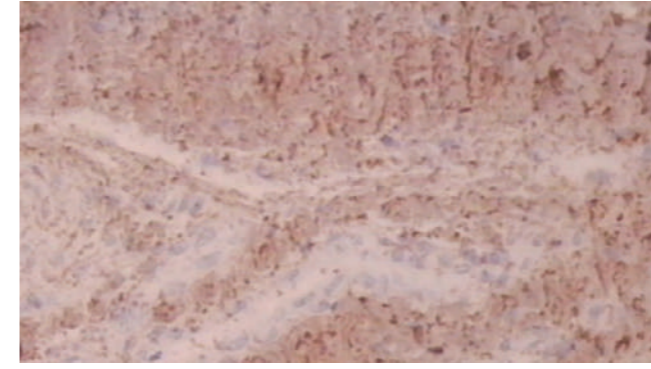
**FIGURE 4:** Minipig ACL at 24 months demonstrating osseous insertion surrounding Artelon Dynamic Matrix fibers.



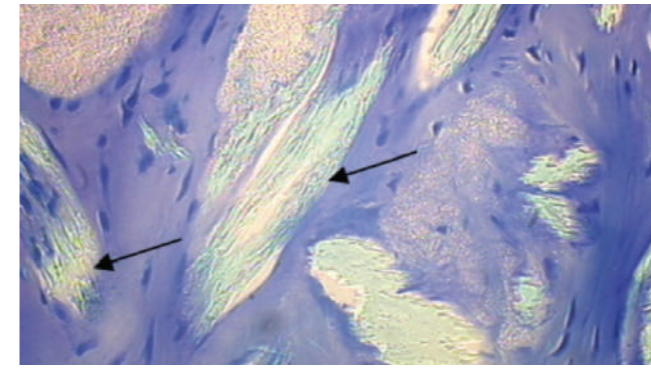
**FIGURE 5:** Minipig ACL at 24 months showing connective tissue between the fibers of the Artelon Dynamic Matrix.



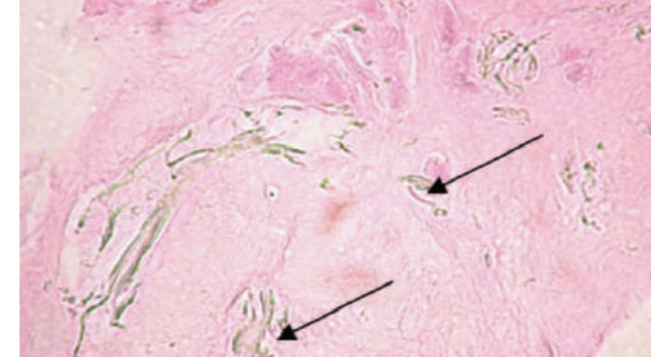
**FIGURE 6:** Human ACL biopsy at 33 months showing connective tissue (black arrows) intimately integrated within the Artelon Matrix Fibers (red arrows).



**FIGURE 7:** Human ACL biopsy at 33 months stained for type 1 collagen (brown) within the Artelon Matrix.



**FIGURE 8:** Human ACL biopsy at 39 months illustrating degradation of Artelon Dynamic Matrix fibers (black arrows) and intimate integration of connective tissue (blue).



**FIGURE 9:** Human ACL biopsy at 61 months demonstrating late stage degradation of Artelon Matrix fibers (black arrows).

**HUMAN EVIDENCE**

Biopsies of Artelon's Dynamic Matrix were taken from the ACL's of 4 patients at 33 and 61 months following implantation. Analysis of the human samples demonstrated a lack on inflammation and elongated fibroblasts oriented in line with the Artelon Matrix fibers. Immunohistochemistry identified the prevalence of type I collagen and new vascularity within the connective tissue. Progressive degradation of the Artelon Matrix fibers was also observed at both time points.<sup>7</sup>

**DYNAMIC MATRIX WITH KNOWN RESULTS**

- Proven biocompatibility
- Less inflammatory than common biomaterials (Titanium, Polystyrene)
- Vascular regeneration
- Long term matrix resorption
- Intimate bony ingrowth within insertional tunnels
- Type I collagen regeneration

**DYNAMIC RECONSTRUCTION**

**RESTORES KINEMATICS (IMMEDIATELY)**

- Stretches like native tendon & ligament
- Permits anatomic motion around joints with correct muscle/tendon length and proprioception
- Creates a reconstruction stiffness similar to uninjured tissue.

**RESISTS NECROSIS**

- Artelon's Dynamic Matrix is proven to be non-inflammatory and mechanically stable throughout the phases of healing.
  - 1Y Maintains 90% of its mechanical properties, grafts lose 50-90% of strength in first 6 wks after surgery
  - Less reactive than common biomaterials like titanium, polystyrene and suture

**SUPPORTS REGENERATION THROUGH KINEMATIC LOADING (MECHANOTRANSDUCTION)**

- Healing connective tissues require mechanical loads to stimulate remodeling, maturation.
- Artelon's Dynamic Matrix:
  - Promotes load sharing with native tissue, induces biological signaling responsible for tissue regeneration
  - Integrates harmlessly into healing tissue, maintains its properties for 4-5 years, then dissolves

