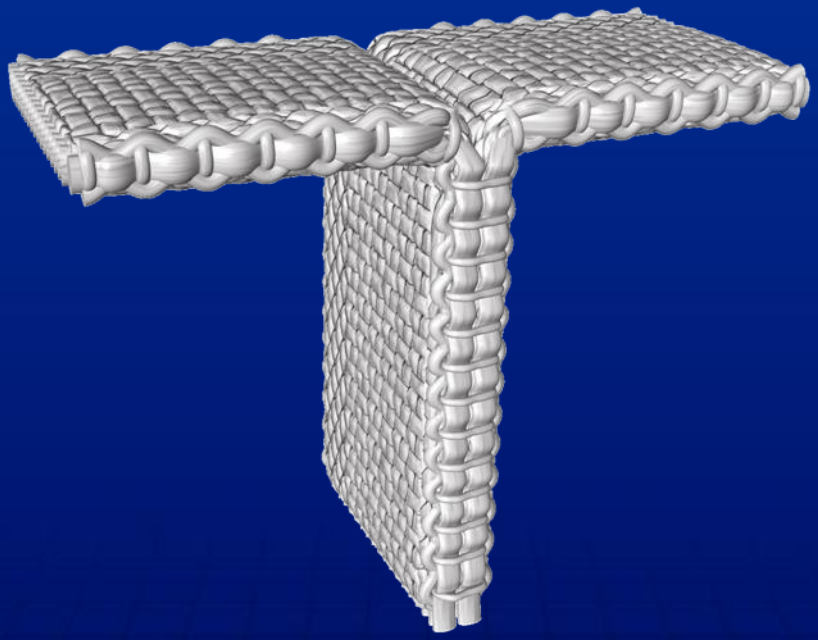
Artelon® CMC Spacer



The Artelon resurfacing concept is a tissue-preserving method for the treatment of osteoarthritis

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Artelon® CMC Spacer - Contents

- Disease States
- Material / Technology
- Patient Selection
- Surgical Technique
- Post – Op
- Clinical Experience
- Future Studies

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Artelon® CMC Spacer

Disease States

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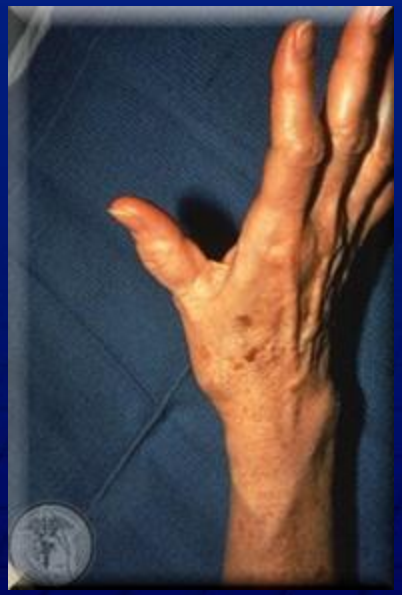
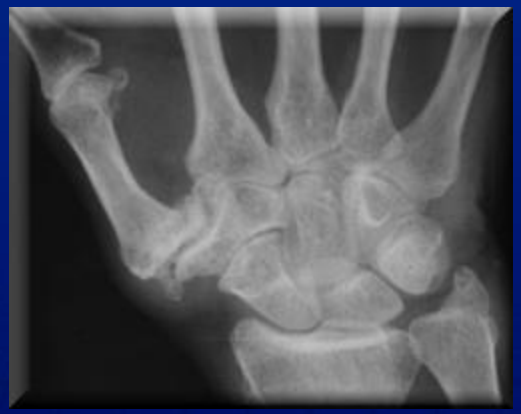
Thumb CMC Joint Arthritis

The most common surgically reconstructed area in arm due to OA





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CMC Osteoarthritis

- Affects 16-25% of postmenopausal women
- Causes pain, swelling, instability, deformity & loss of motion
- Radiographic evidence of basal joint arthritis
  - 1 in 4 women
  - 1 in 12 men

CMC-I Arthritis Demographics

- Incidence
  - Prevalence in postmenopausal women
    - Isolated carpometacarpal – 25%
    - Scaphotrapezial – 2%
    - Combined - 8%
  - Symptomatic Arthritis
    - 28% isolated and 55% combined

Treatment Options – Non-Surgical

- Activity Modification
- Medical Therapy
  - Anti-Inflammatory medications
  - Intra-articular Steroid Injection
- Motion Restriction
  - Splinting (Thumb spica)
    - Approximately 50% Improvement in pain after 6 mo., less with more advanced stages

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Treatment Options - Surgical

- Surgical intervention may be considered in cases of severe persistent pain limiting patient's function
- Tx's Commonly Used Prior to Artelon Introduction
  - Ligament Reconstruction
  - Trapezium resection arthroplasty with tendon interposition ("Anchovy")
  - Total Joint Replacement
  - Arthrodesis (fusion)

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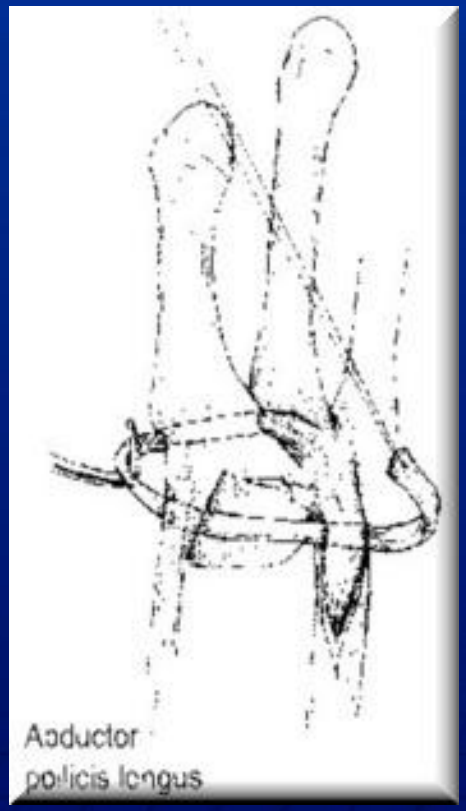
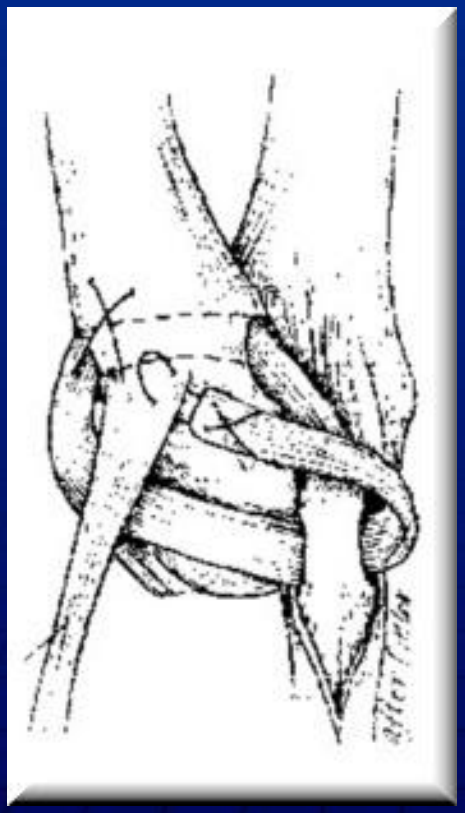
Ligament Reconstruction





Eaton Stage 1

Addresses laxity of the volar oblique ligament

- Radial ½ of FCR* is passed through hole made in MC base
- Anchored with appropriate tension

* Flexor Carpi Radialis

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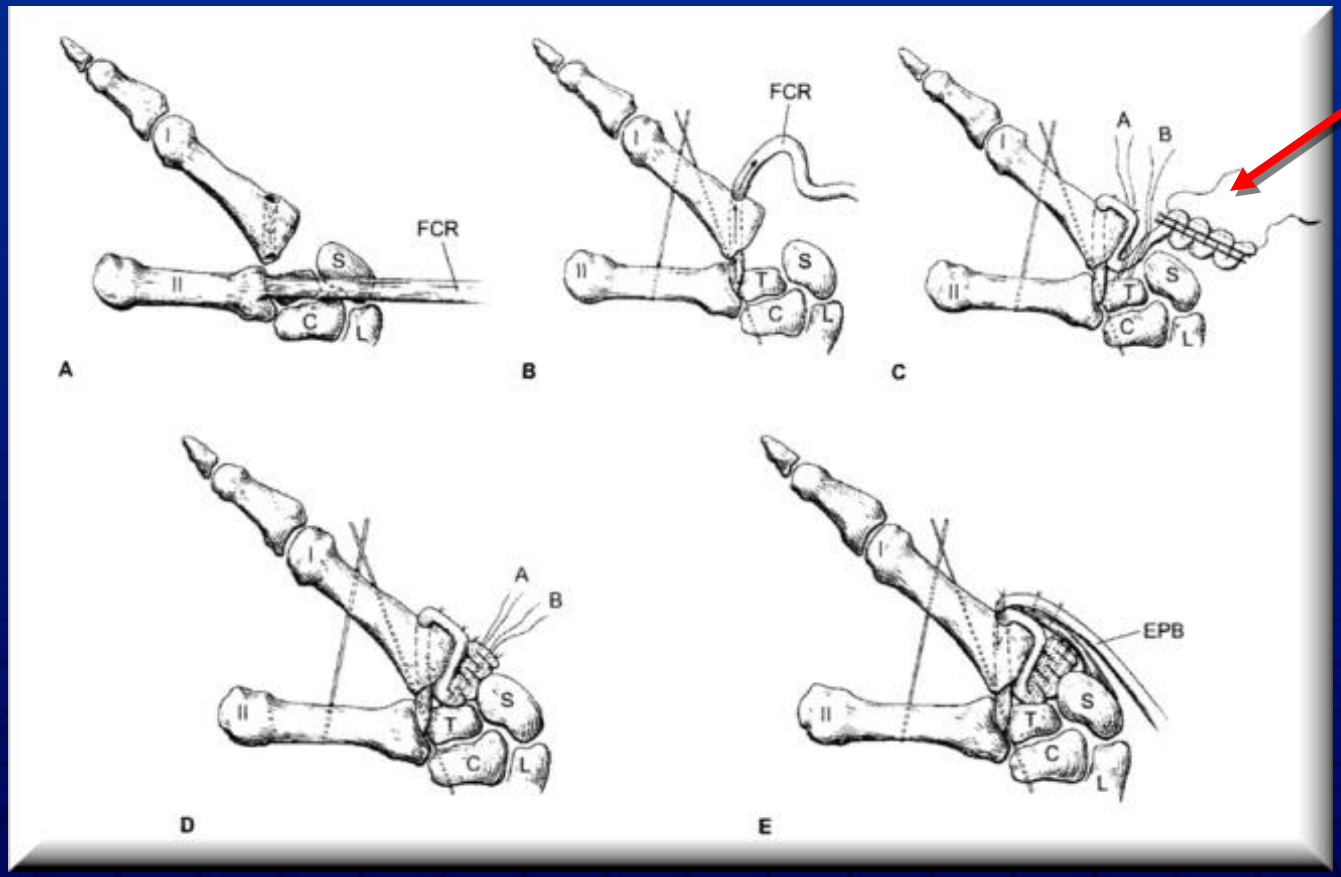
Ligament Reconstruction Tendon Interposition (LRTI – "Anchovy")

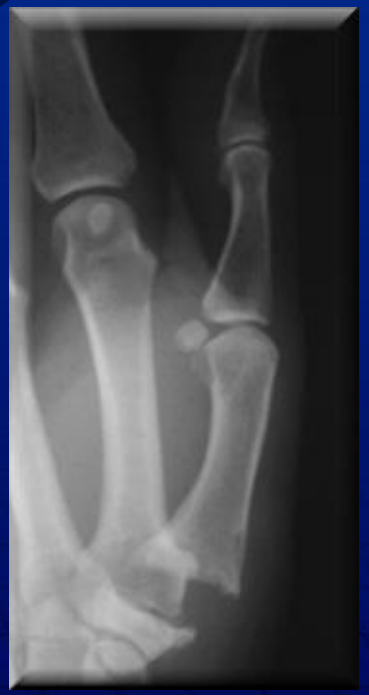
Eaton Stage II / III / IV disease

- Removal of the involved joint
  - Partial trapeziectomy Stage II / III
  - Total trapeziectomy Stage IV
- Slip of FCR to stabilize lax volar oblique ligament
- End of FCR then coiled and inserted into defect to maintain length and provide painless mobility

Ligament Reconstruction Tendon Interposition (LRTI)



"ANCHOVY"



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Tendon Interposition Arthroplasty Study Results

Results

- **Rayan et al, 1997**
  - 28 patients, follow-up 3 years;
  - Pain reduction very good in > 90%, 87% satisfaction,
  - Improved functional mobility.
- **Damen A. Et al 1996**
  - 45 Patients, avg. follow-up 103 months;
  - Function improved by 90%
  - Pain reduced in 93%, mobility was equal to that of the unoperated side

However...

- **Requires 3-6 month recovery**
- **Requires harvest of FCR**
- **Results in decreased pinch strength**
- **Increased incidence of thumb shortening**

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Artelon® CMC Spacer

Material / Technology

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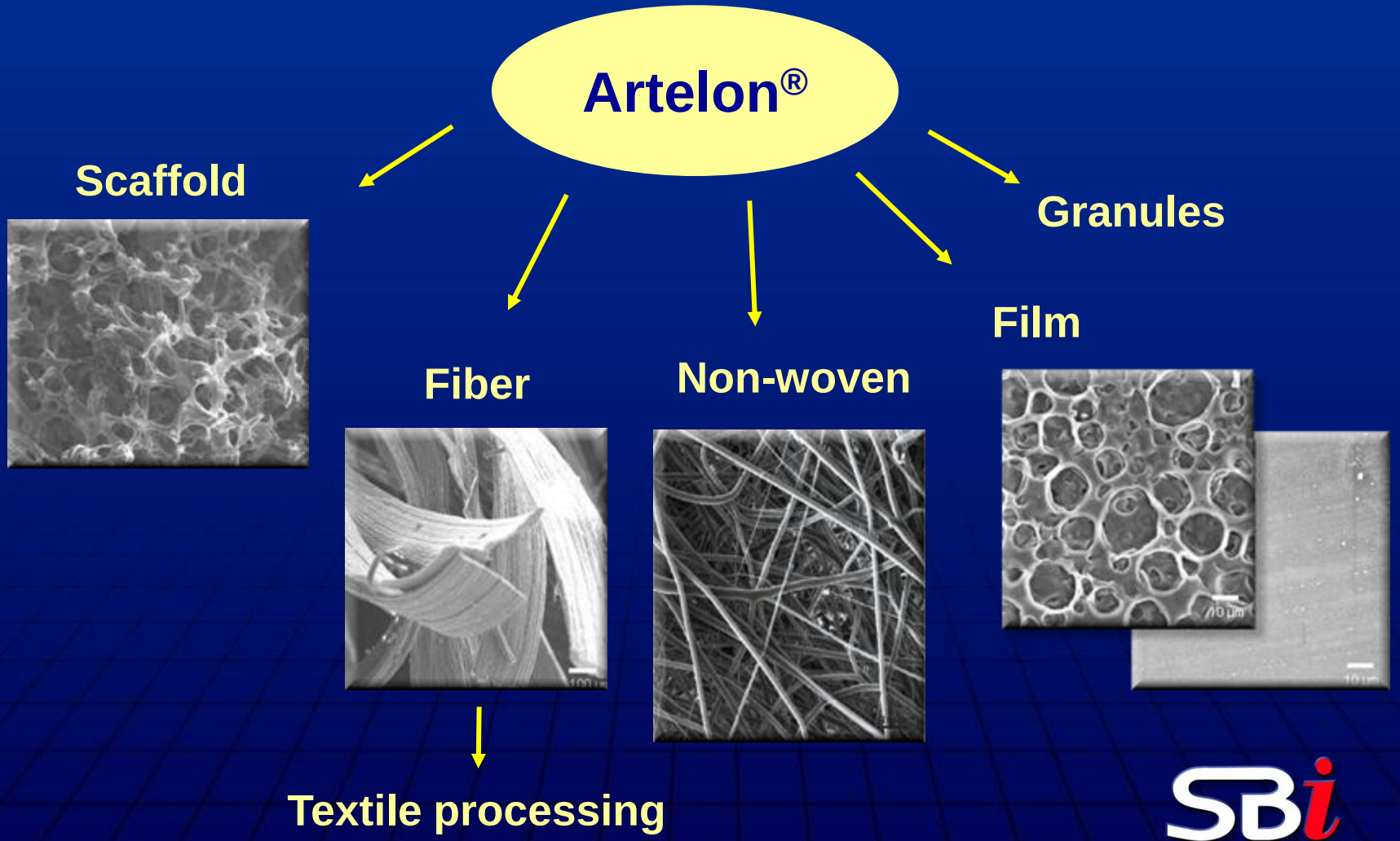
Versatility of Artelon®



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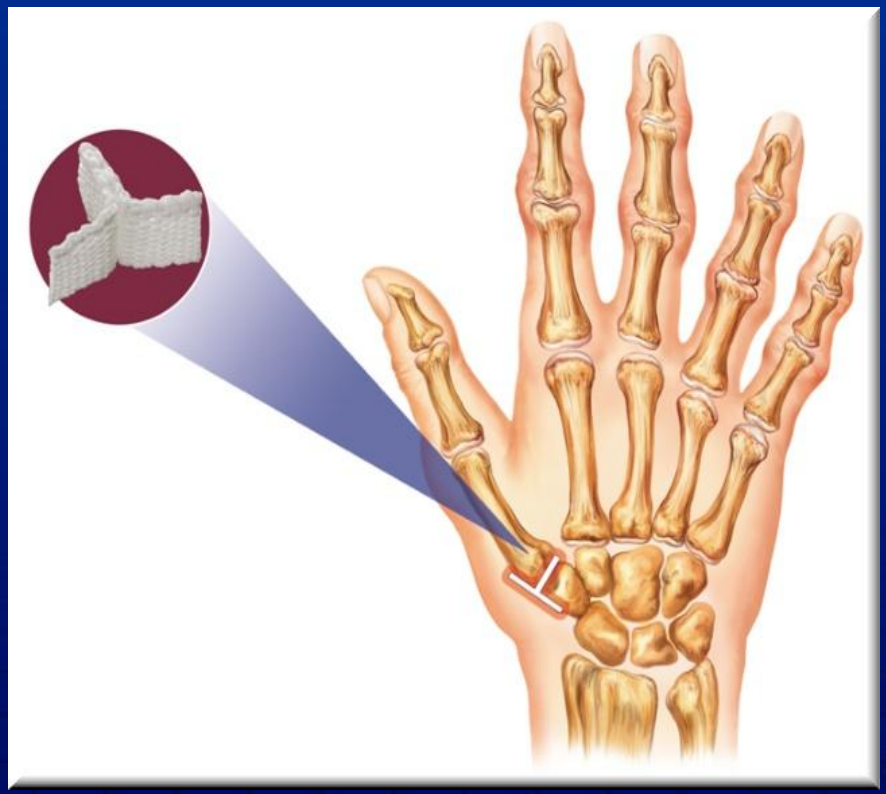
Artelon Applications

Artelon CMC Spacer - Indication

Indication

ARTELON CMC Spacer is intended to be implanted into the first carpometacarpal joint (CMC-I) as an interpositional spacer between the trapezial bone and the first metacarpal bone.

The device is intended to be used in thumb disabilities caused by osteoarthritis.



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Artelon CMC Spacer – Mode of Action

- Artelon CMC Spacer is a T-shaped device, where the vertical portion separates the bone edges of the CMC-I joint and the horizontal portion stabilizes the joint.

- By avoiding the removal of the trapezial bone, this tissue-preserving concept maintains the anatomy of the CMC-I joint intact.

Artelon CMC Spacer – Description

ARTELON® CMC Spacer is a woven one-piece device made of ARTELON®, a polycaprolactone based polyurethaneurea. Artelon CMC Spacer is supplied sterile.

Artelon copolymer at the beginning of manufacturing process

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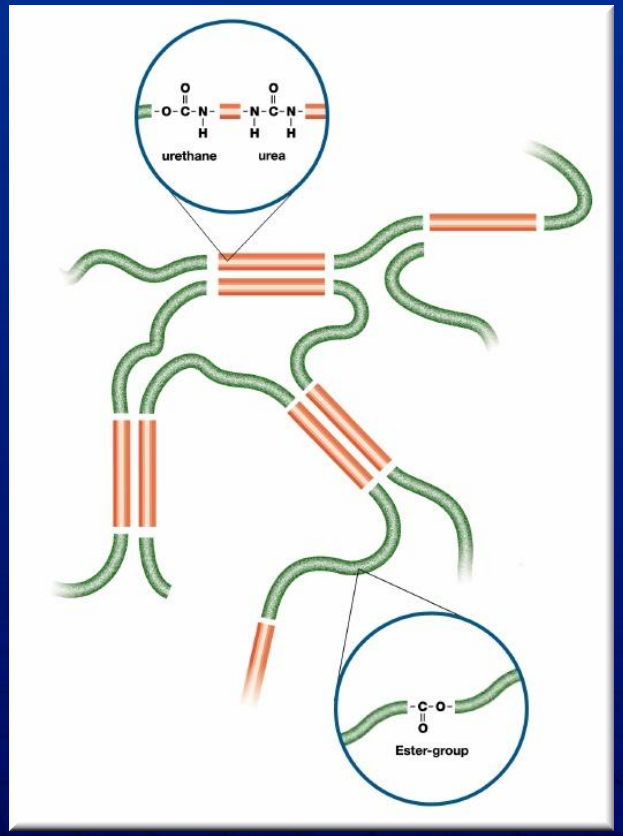
Artelon®

- New co-polymer biomaterial built on well known chemical components (PUUR)
  - Polycaprolactone (GREEN)
  - Urethane Urea (RED) (urethane & urea groups)
- Biocompatible & well tolerated in both bone & soft tissue
- More than ten years of clinical experience
- Possible to create scaffolds for long term support
- Predictable long term degradation



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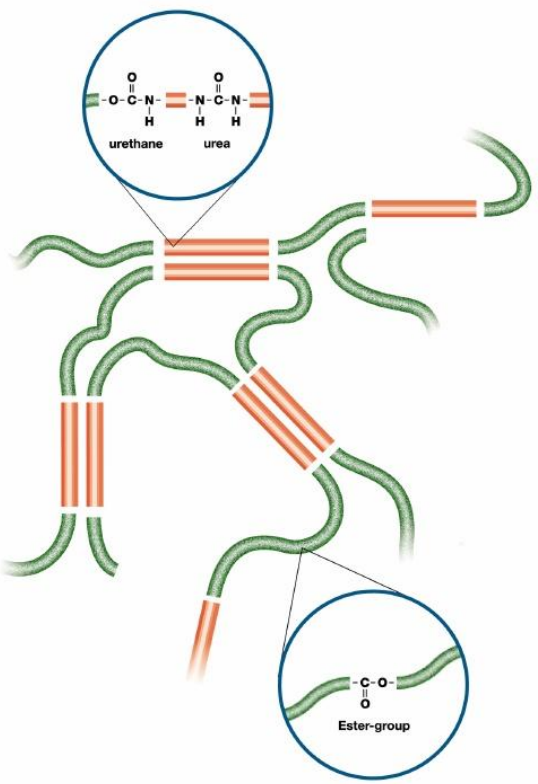
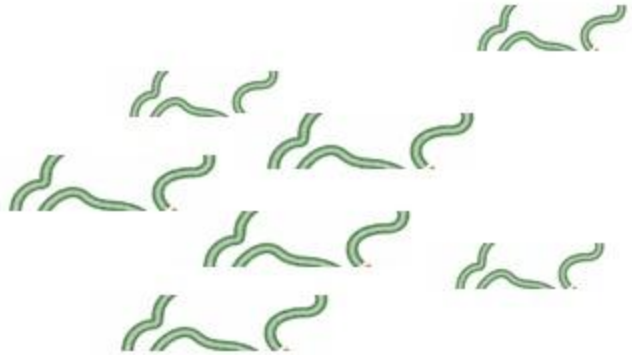
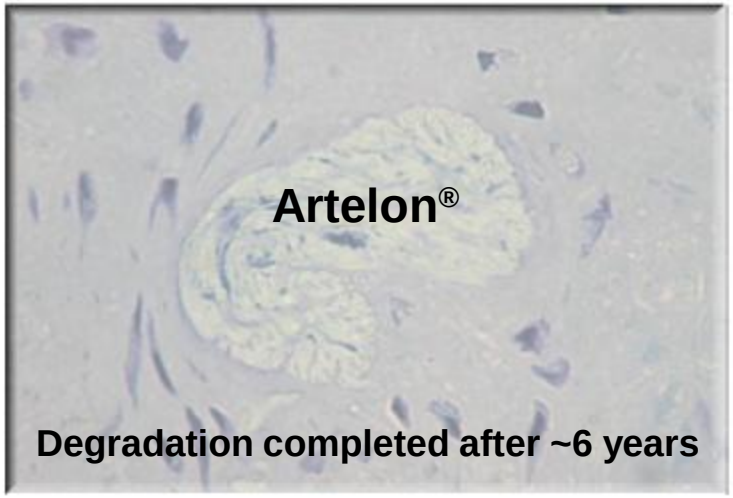
Artelon® Degradation



+ water

Polycaprolactone Degrades (~50%)



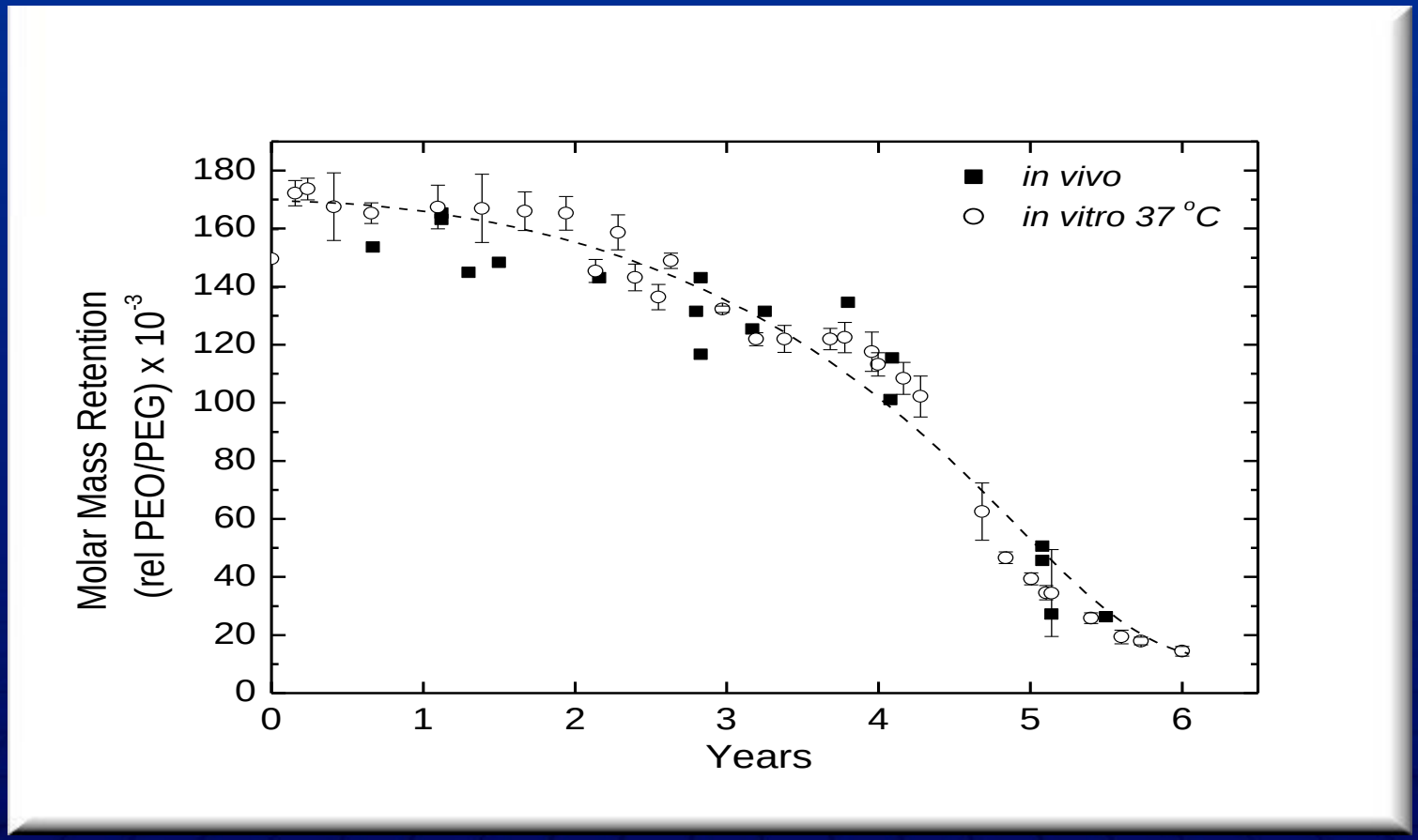


Degrades by hydrolysis –

Not affected by enzymes

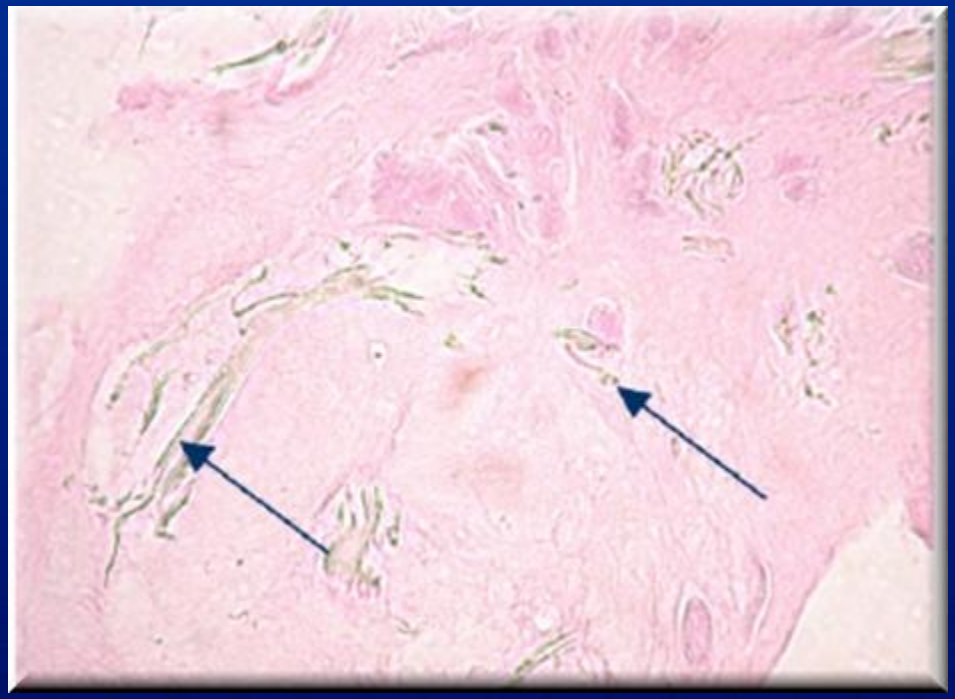
Urethane Urea Remains (~50%)

In Vivo vs. In Vitro Degradation



Similar profiles indicate that the only degradation process is hydrolosis.

Artelon - Degradation Products



~50% of Artelon degrades and is resorbed by the body.

Degradation products have been shown to be both safe and tissue compatible and do not cause an acidic environment.

Biopsy from patient 61 months after implantation with Artelon Augmentation ACL Device. Arrows denote irritation free interface between Artelon and host tissue.

~50% of the initial mass will remain at the implantation site and is incorporated into the surrounding host tissue ***without eliciting any inflammatory or foreign body response***.

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Biocompatibility

Collagen II producing chondrocytes have been seen in close contact with Artelon CMC Spacer.

Animal and human studies have revealed excellent compatibility between host tissue and Artelon

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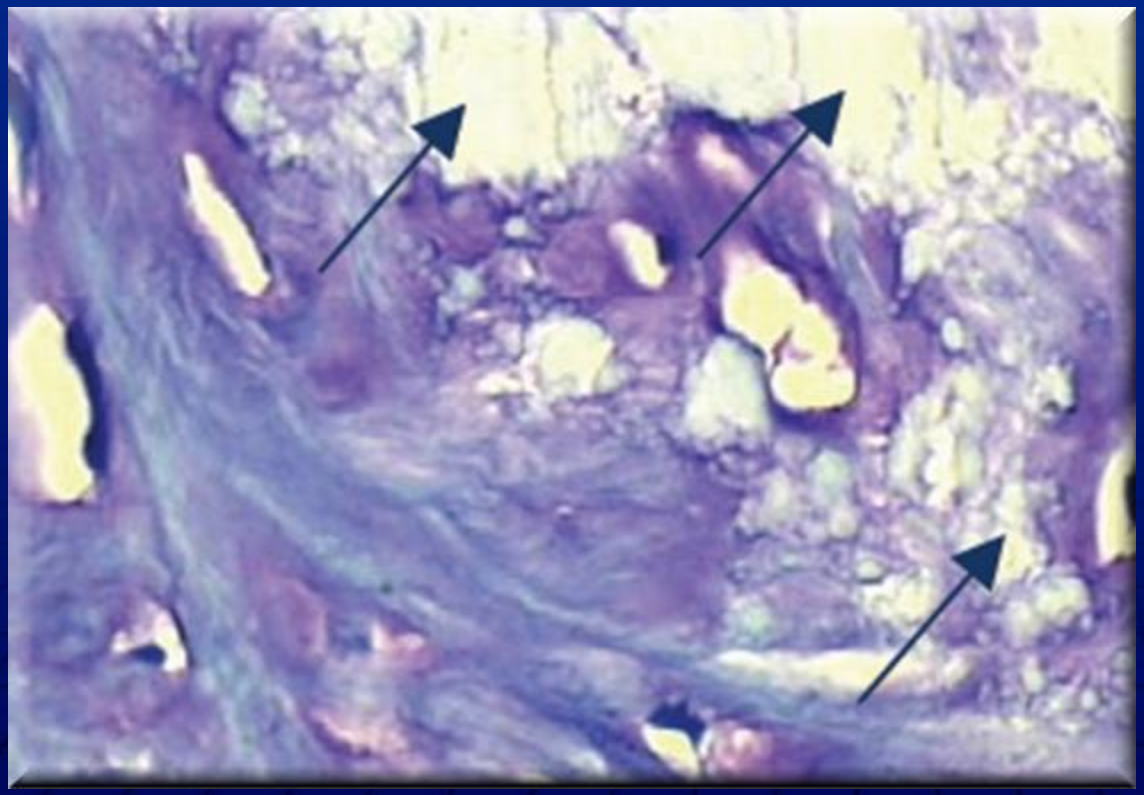
Artelon Biocompatibility In Bone

Human studies have revealed excellent biocompatibility between host tissue and Artelon® in different indications.



Toluidine blue stain, 6 months after implantation – Artelon CMC Spacer

Biopsy showing excellent integration of the Artelon biomaterial in the surrounding host bone without signs of encapsulation.

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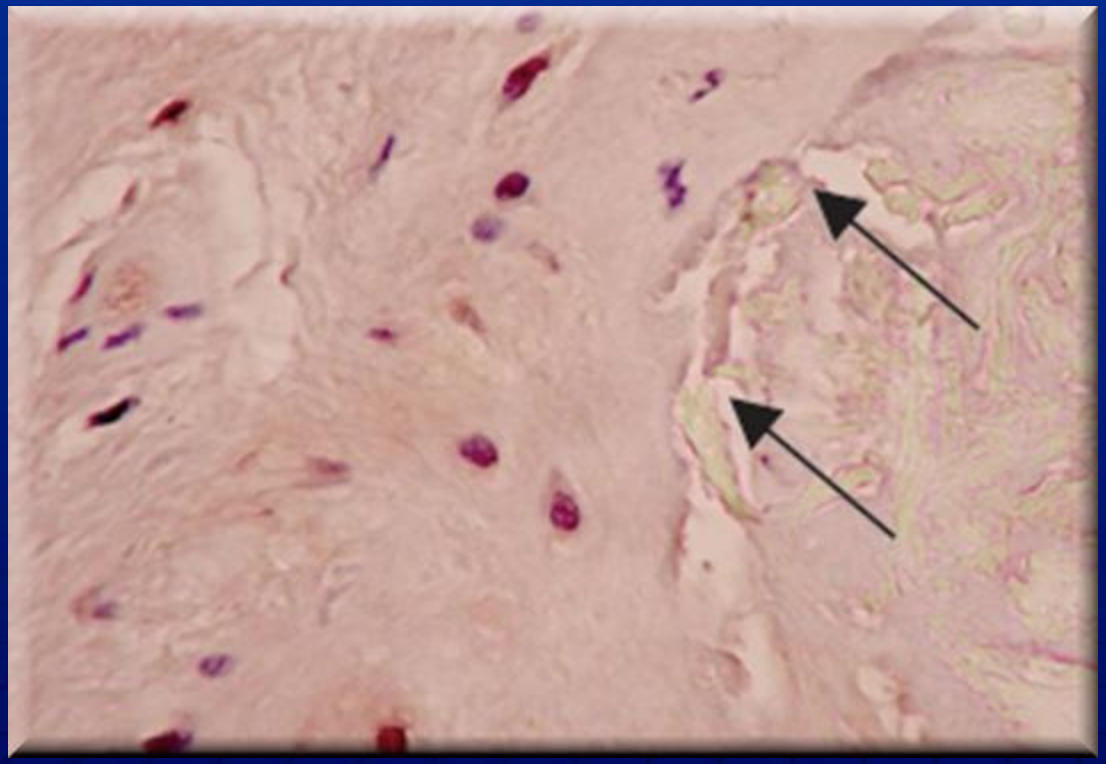
Artelon Biocompatibility In Soft Tissue



Safranin-O stain, 3 months after implantation

Artelon in close contact with collagen II expressed by chondrocytes

Indicates close, irritation-free incorporation with cartilage

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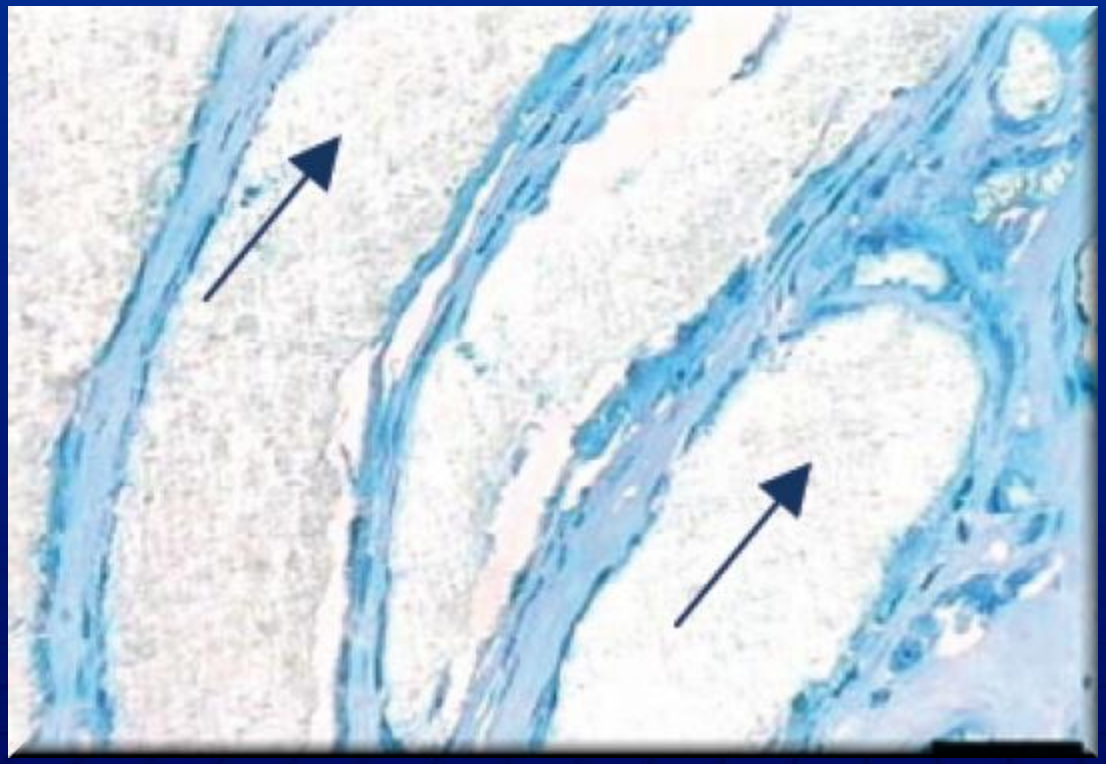
Normal Biologic Incorporation



Orientation of fibroblasts and collagen parallel to the Artelon fibers, in the direction of the tensile load

Toluidine blue stain, 33 months of implantation, Artelon Augmentation Device ACL

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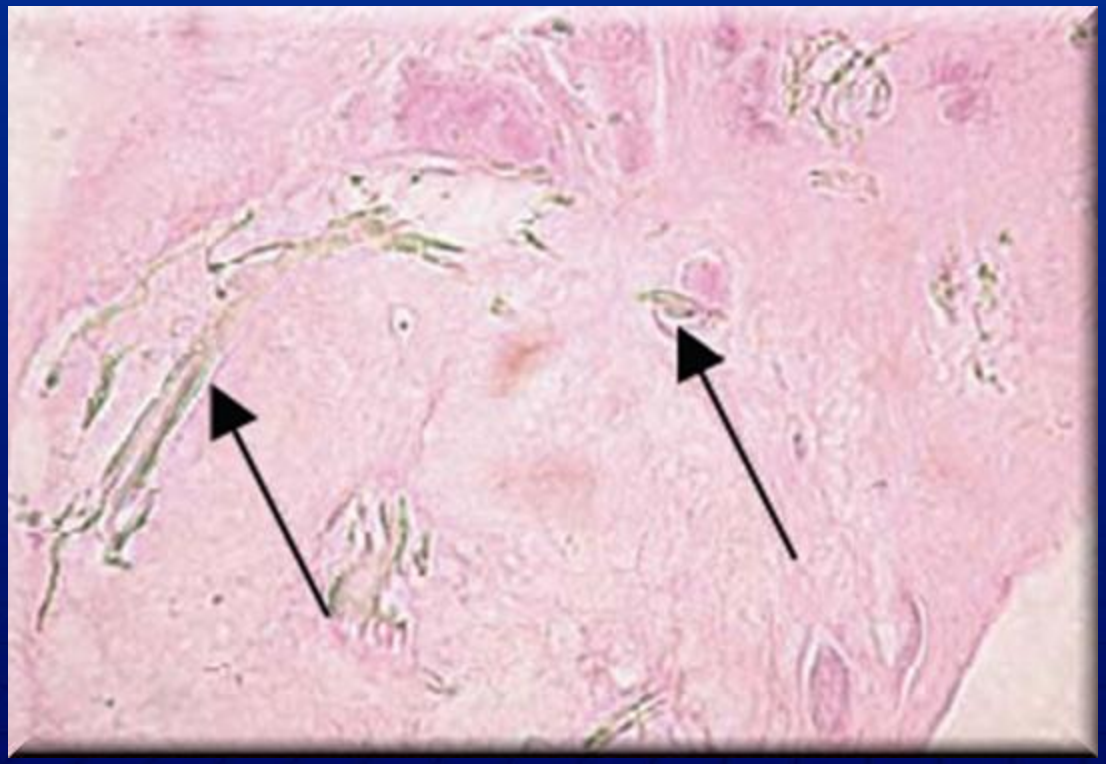
Long Term Degradation & Safety



Hematoxylin-eosin stain, Artelon Augmentation Device ACL

61 months after implantation, the degraded Artelon is well incorporated in human ligament tissue

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Safety of Polyurethane-urea

- Polyurethane-ureas have been ***used since the 1970s*** in applications such as catheters, artificial hearts, blood vessels, pacemaker insulation, wound dressings, dialysis, etc.

- Artelon® has gone through ***all relevant safety studies*** (cytotoxicity, mutagenicity, hypersensitivity, in vivo implantation, etc.)

- The Artelon material has been used in over 3,500 patients with ***over 10 years of clinical experience*** on the original (ACL) patients

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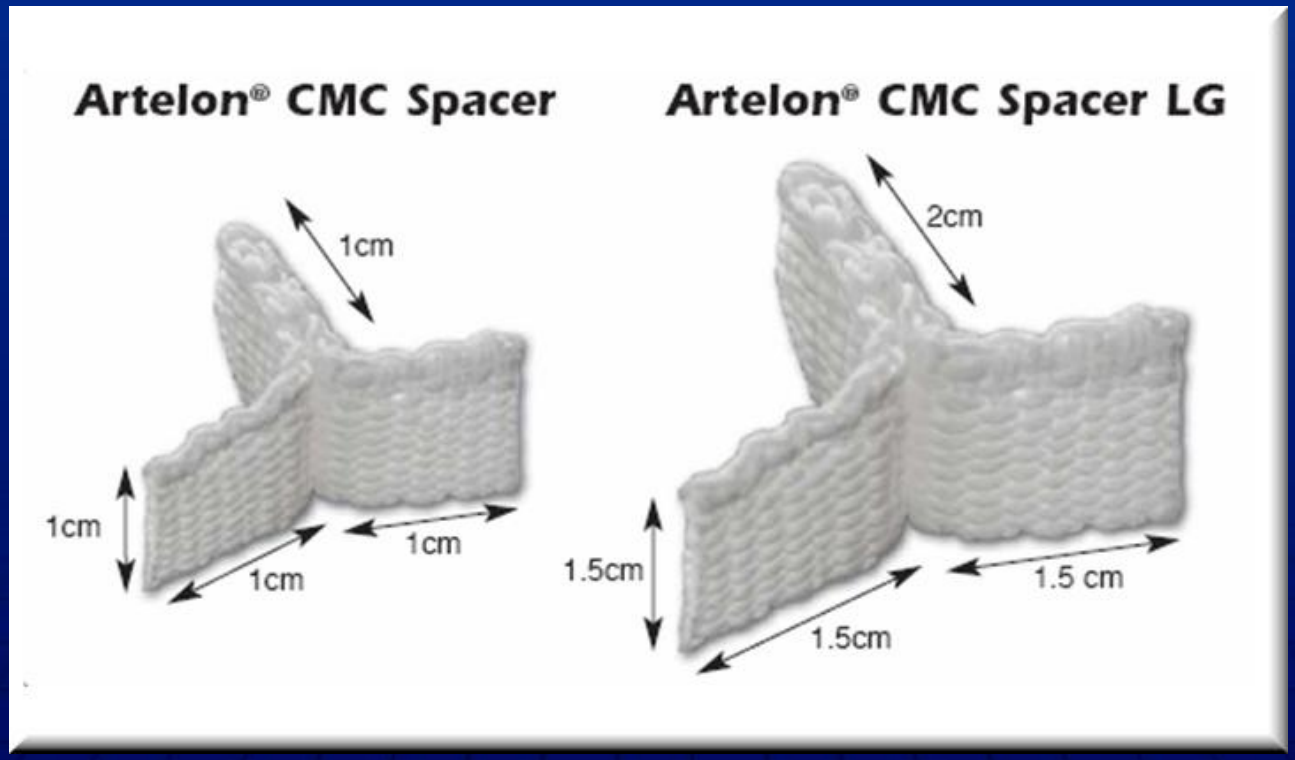
Artelon® Sizes

Standard & Large Artelon



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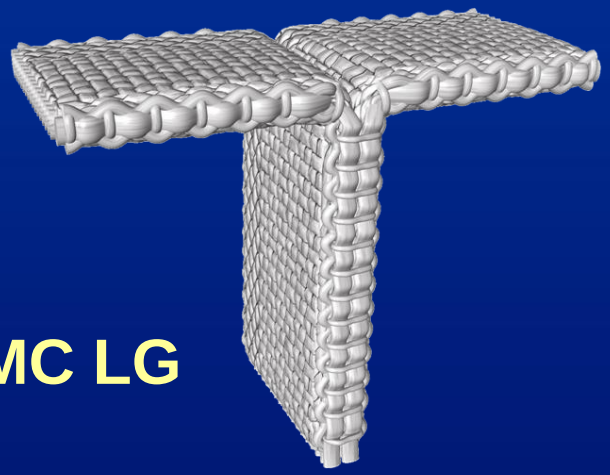
New Products In The Artelon Spacer Family

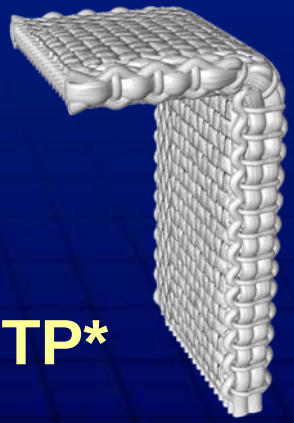


CMC LG

Arthro

STT

DRU*



MTP*

* Not Available For Sale in the U.S.

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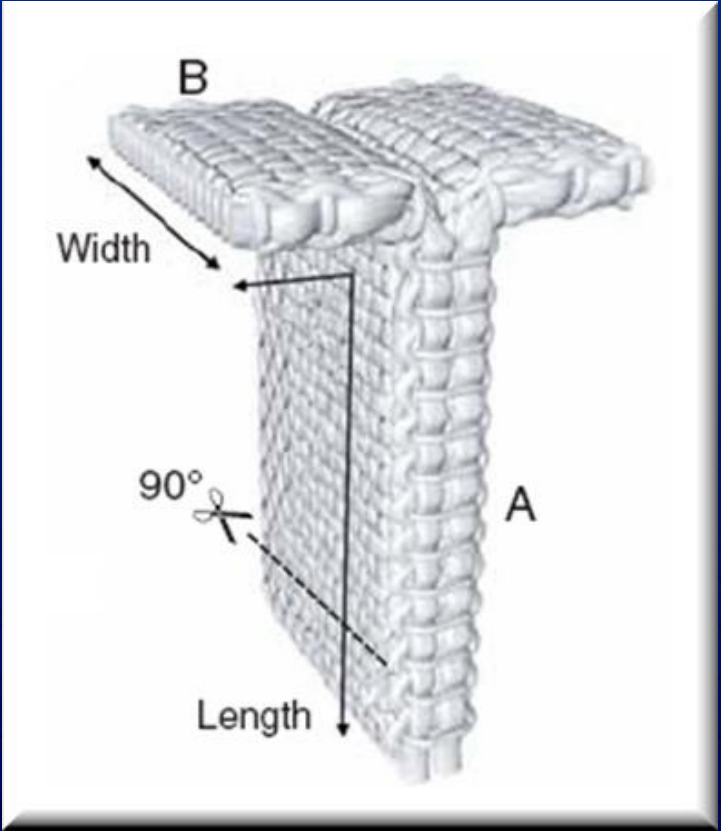
Artelon Sizes

Artelon® CMC Spacer Arthro



Artelon CMC Spacer Arthroscopic	
Wing Length (B)	5mm
Wing Width (B)	14mm
Vertical Length (A)	20mm
Vertical Width (A)	14mm

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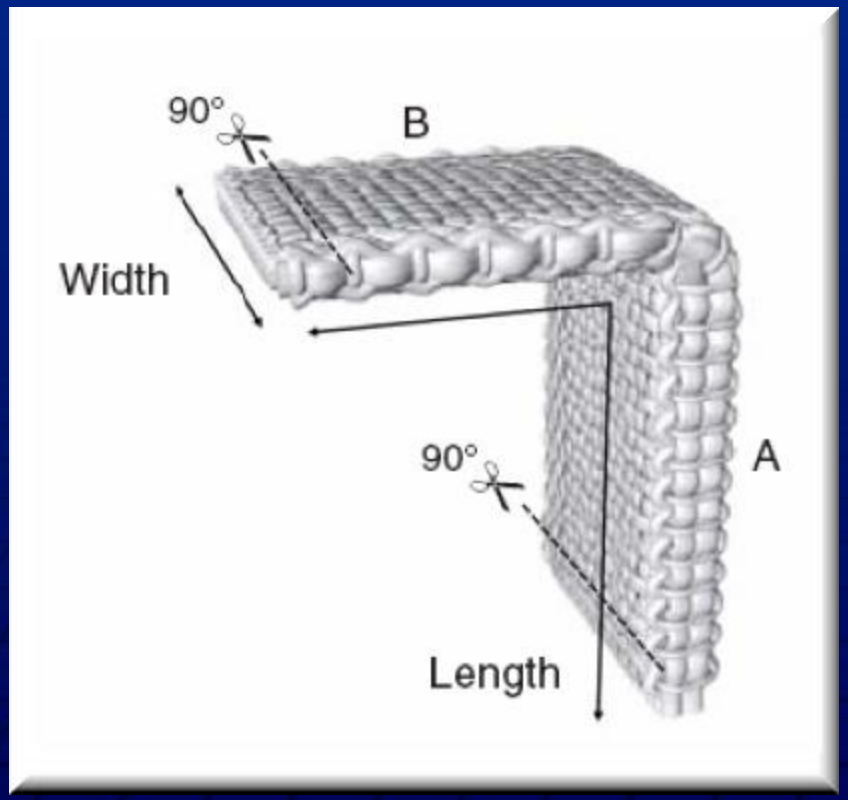
Artelon Sizes

Artelon® STT Spacer



Artelon® STT Dimensions	
Wing Length (B)	14mm
Wing Width (B)	14mm
Vertical Length (A)	20mm
Vertical Width (A)	14mm

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Artelon® CMC Spacer

Patient Selection

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Eaton Classification – CMC OA

- Stage I:
  - Mild joint narrowing or subchondral sclerosis;
  - Mild joint effusion or ligament laxity;
  - No subluxation and no osteophyte formation are present
- Stage II:
  - Narrowing of CMC joint & sclerotic changes of subchondral bone;
  - There may be osteophyte formation at the ulnar side of the distal trapezial articular surface;
  - Mild to moderate suluxation may be present (w/ the base of the first metacarpal subluxated radially and dorsally)
- Stage III:
  - Further joint space narrowing w/ cystic changes and sclerotic bone;
  - Prominent osteophytes are present at the ulnar border of the distal trapezium;
  - Moderate suluxation is present w/ the base of the first metacarpal subluxated radially and dorsally;
    - passive reduction may not be present;
  - Scaphotrapezial may show arthrosis, and there may be a hyper-extension deformity of the MTP joint
- Stage IV:
  - There is similar destruction as in stage III w/ respect to CMC;
  - Scaphotrapezial joint has evidence of destruction;
  - CMC joint is usually immobile and often patients have little pain

Ref: Trapeziometacarpal osteoarthritis: Staging as a rationale for treatment. RG Eaton, SZ Glickel. Hand Clin. Vol 3. 1987. p 455.

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Proper Patient Selection

Patients Types Who Usually Benefit Most From The Artelon CMC Spacer

- Younger, active, high demand patients
- Patients in Eaton Stage II or Early Stage III
- Patients who are looking for an less invasive alternative to more radical procedures like trapeziectomy
- Patients where strength and stability is of significance, such as when the dominant hand is affected

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Proper Patient Selection

Patient Types Who Usually Do Not Benefit As Much From Artelon CMC Spacer Therapy

- Patients with significant subluxation of the CMC-I joint
- Patients with Scapho-trapezial (STT) or other joint pain
  - A new implant has been designed for use in the STT joint
- Patients with significant subluxation of the CMC-I joint (>25% - 50%)
- Patients with inflammatory conditions (rheumatoid arthritis, lupus, etc.)
- Patients with significant hyperextension of the MP joint
- Patients with adduction deformity

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Artelon® CMC Spacer

Surgical Technique

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Keys To A Successful Artelon CMC Spacer Case

- Proper Patient Selection
- Secure Fixation of the Implant
- Post-op x-ray for later comparison
- Full Immobilization of the Joint (5-6 weeks)
- Proper Rehabilitation Program
- Give the Joint Capsule Time to Heal (12 weeks)
- Look For Fixation Issues if Pain Persists

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Artelon CMC Spacer – Fixation

Secure fixation is critical to procedural success

- Typical Fixation Techniques
  - Sutures
  - Suture Anchors (most common method)
  - Screws

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Artelon CMC Spacer – Fixation

- Sutures
  - Do NOT Use Resorbable Sutures
    - They tend to resorb too quickly. Wings may not have a chance to securely fixate.
- Suture Anchors
  - Resorbable or Non-resorbable Anchors
    - Resorbable - be sure they will remain secure for AT LEAST 6 Months.
    - Resorbable Anchor with Non-resorbable suture materials are most common & preferred.

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Artelon® CMC Spacer
Secured with Sutures

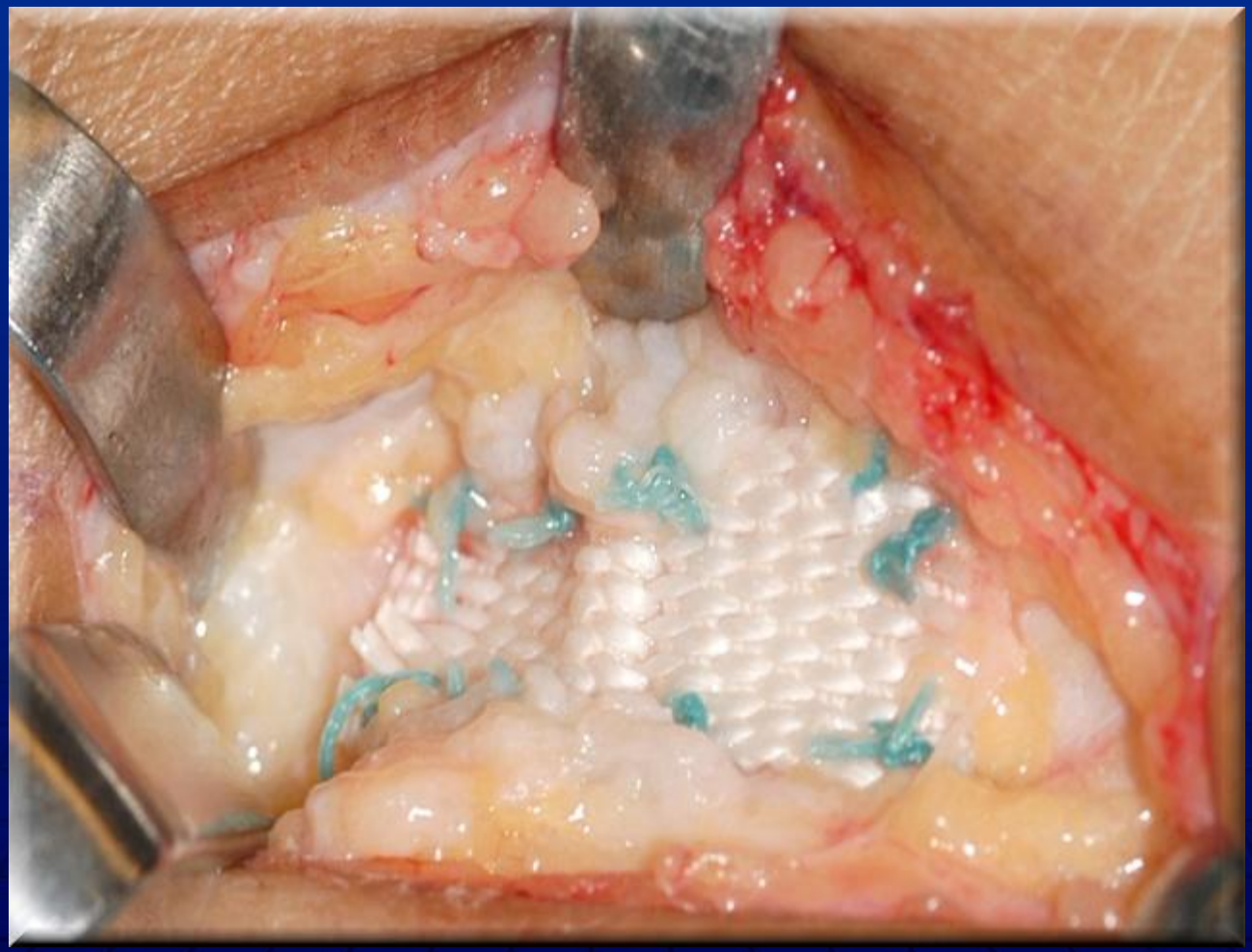


Photo Courtesy of Harold Kleinert, MD

Artelon® CMC Spacer

Secured with Suture Anchors

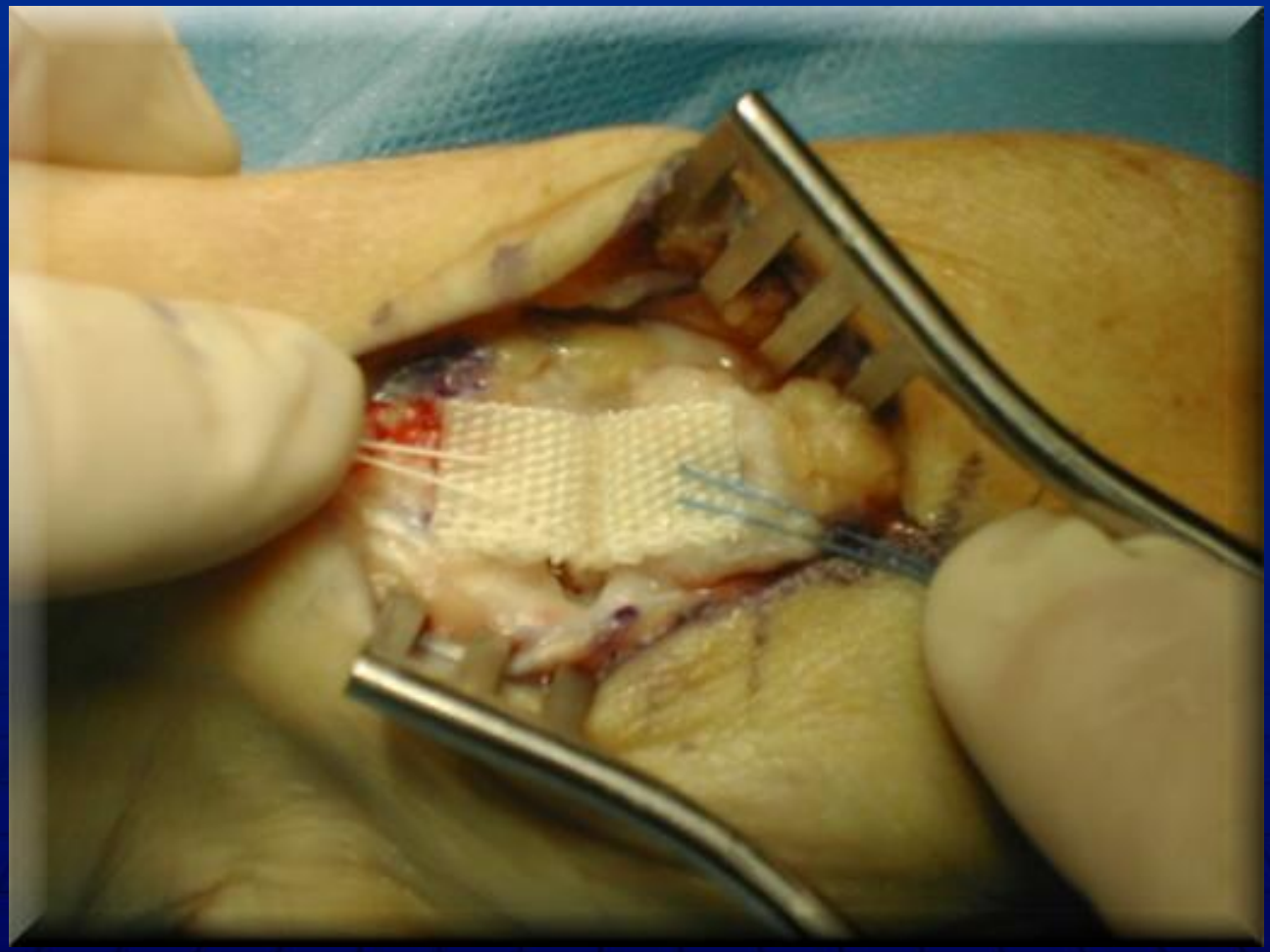
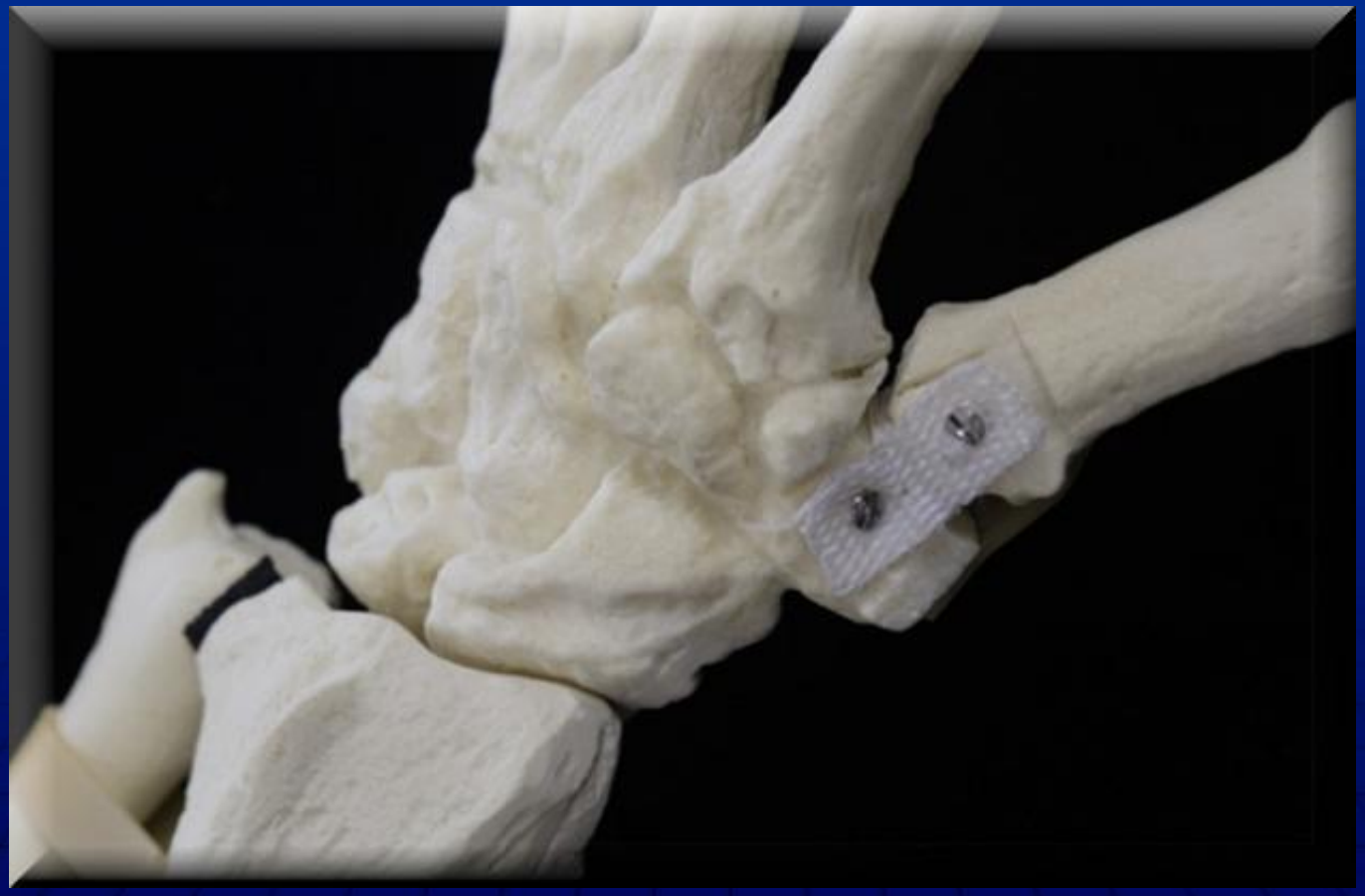


Photo Courtesy of Terrence O'Donovan, MD

Artelon® CMC Spacer
Screw Fixation



Note: Be sure that stable, bi-cortical fixation has been achieved

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Artelon CMC Spacer – Indication

- Artelon CMC Spacer is intended to be implanted into the first carpometacarpal joint (CMC-I) as and interpositional spacer between the trapezial bone and the first metacarpal bone.
- The device is intended to be used in thumb disabilities caused by osteoarthritis.

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Artelon CMC Spacer – Surgical Technique

- Soak Artelon CMC Spacer in sterile saline for at least five minutes before use.

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Artelon CMC Spacer – Surgical Technique

- Open the CMC-I joint with a dorsal incision

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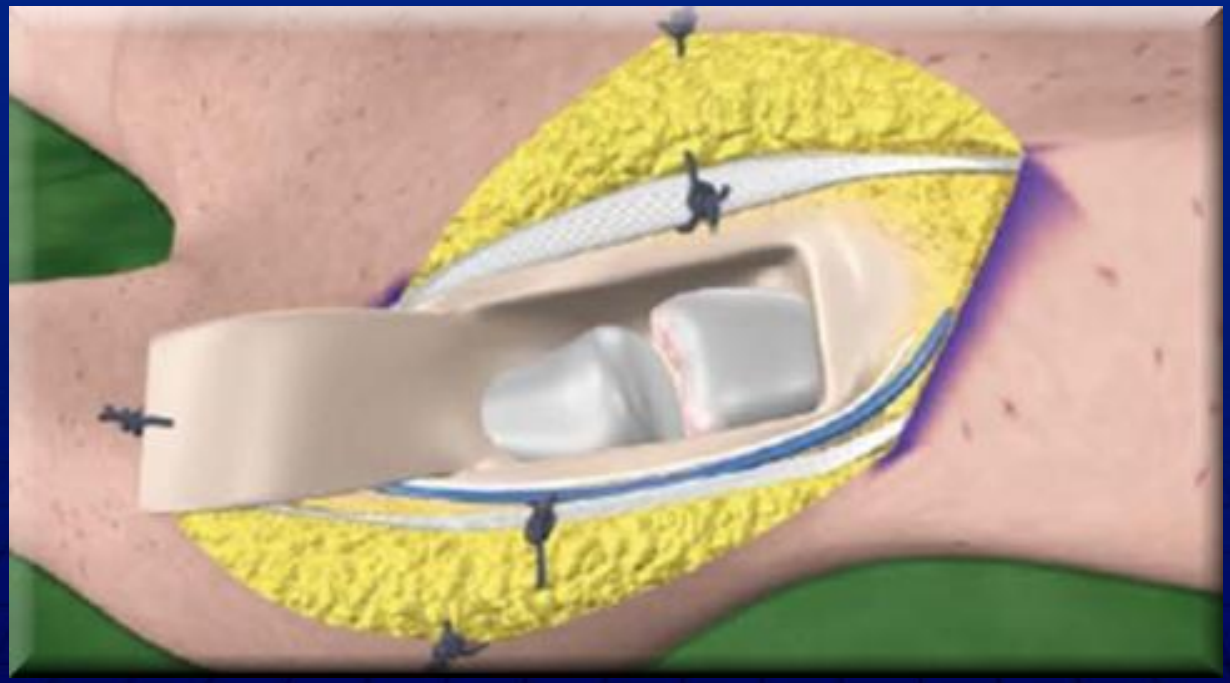
Artelon CMC Spacer – Surgical Technique

- Dissect a periosteal flap from the trapezial bone including the joint capsule



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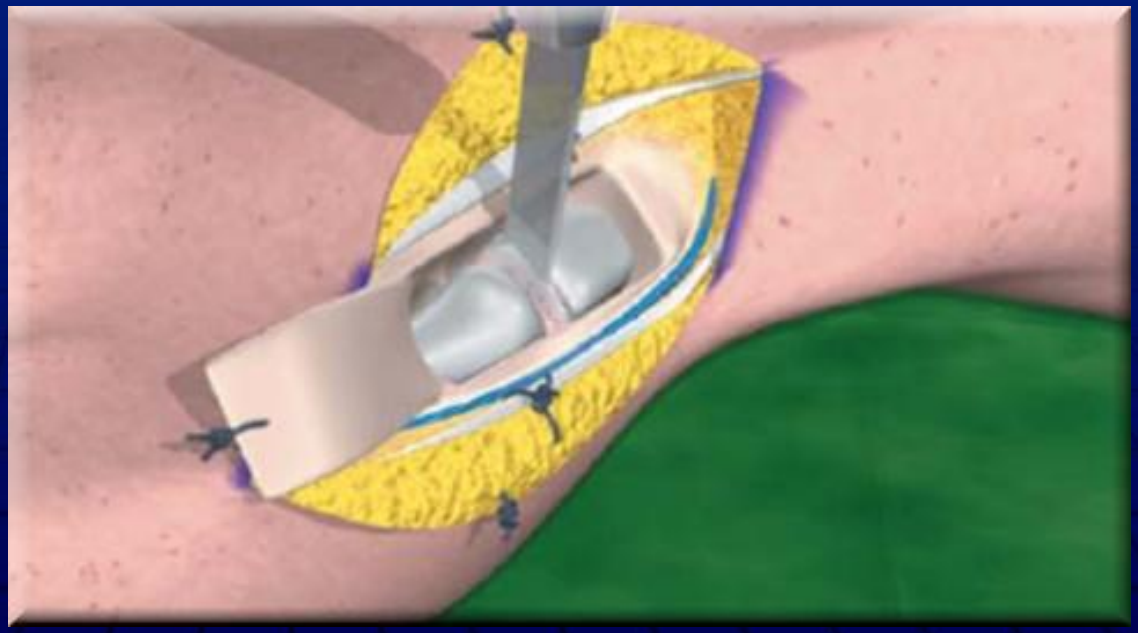
Artelon CMC Spacer – Surgical Technique

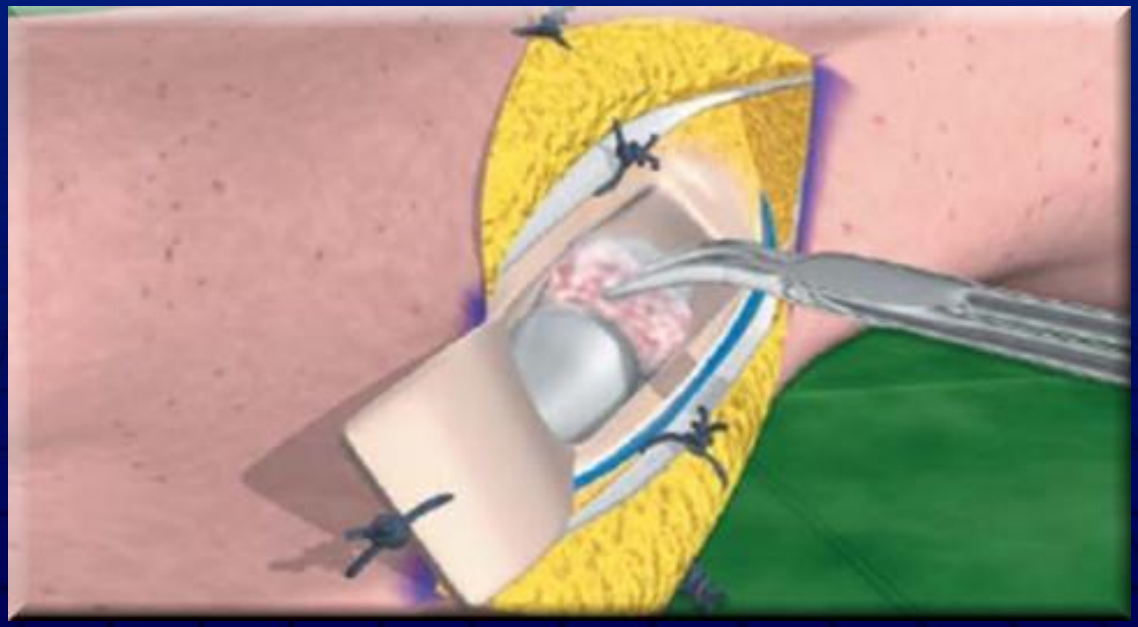
- Resect the distal joint surface along with 1-2 mm of subcondral bone on the articular surface of the trapezial bone
- Leave the articular surface of the metacarpal bone intact



Artelon CMC Spacer – Surgical Technique

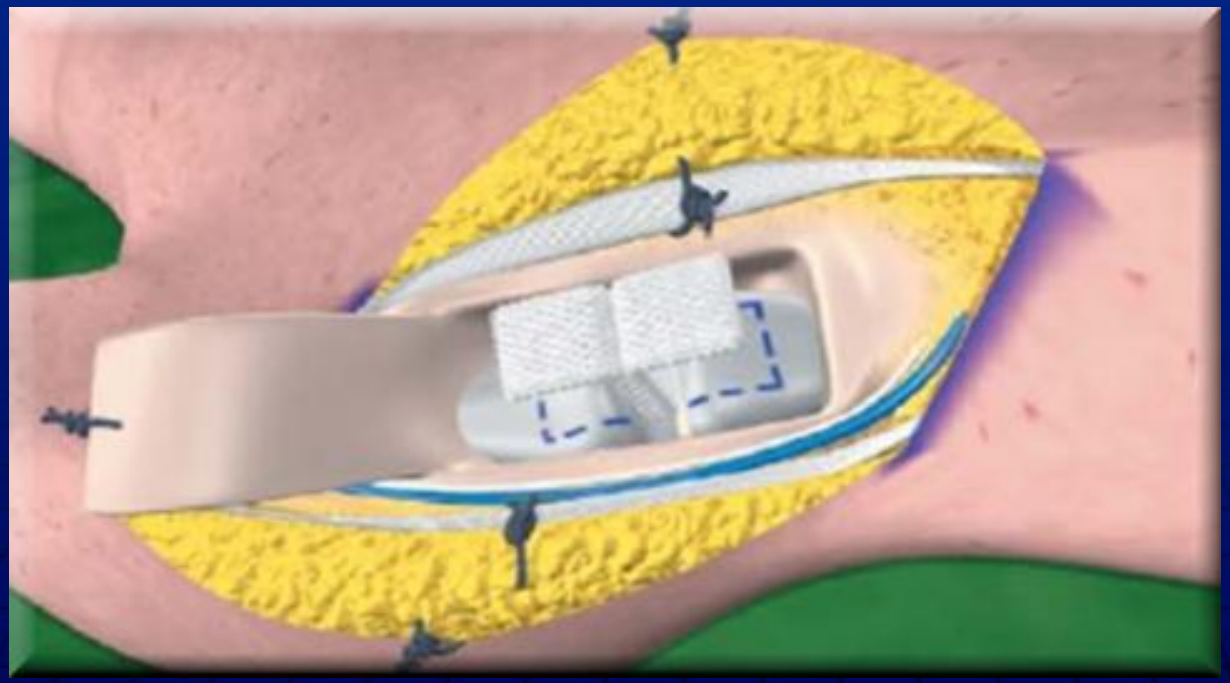
- Remove osteophytes from the joint lines
- It is essential for a good result to create a bleeding surface on the trapezial bone

Keep an intact surface on the metacarpal bone in order to create a new joint surface to articulate against



Artelon CMC Spacer – Surgical Technique

- Mark the position of the wings



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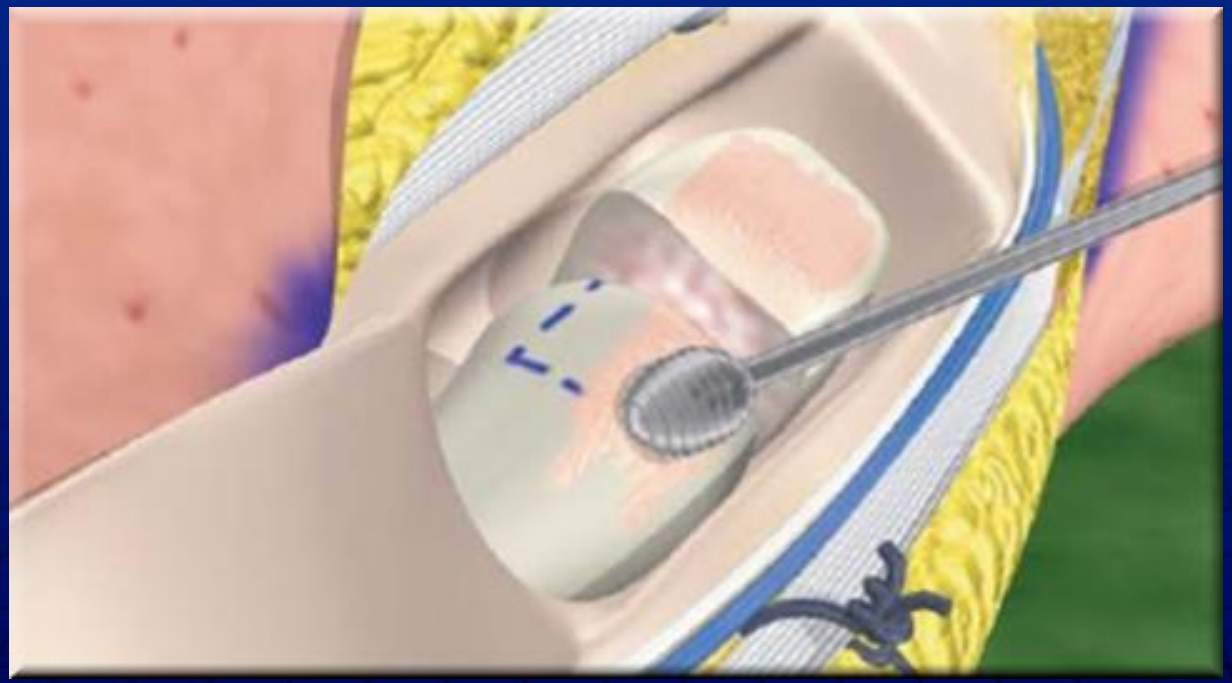
Artelon CMC Spacer – Surgical Technique

- Flatten the dorsal cortical bone in the marked area with a burr to create a bleeding surface



Remove Only Enough Cortical Bone To Achieve A Bleeding Surface

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Artelon CMC Spacer – Surgical Technique

Fixation with screws

- Drill the screw pilot hole through the center of the wing making sure to penetrate the volar, cortical bone. Always use sharp drills.

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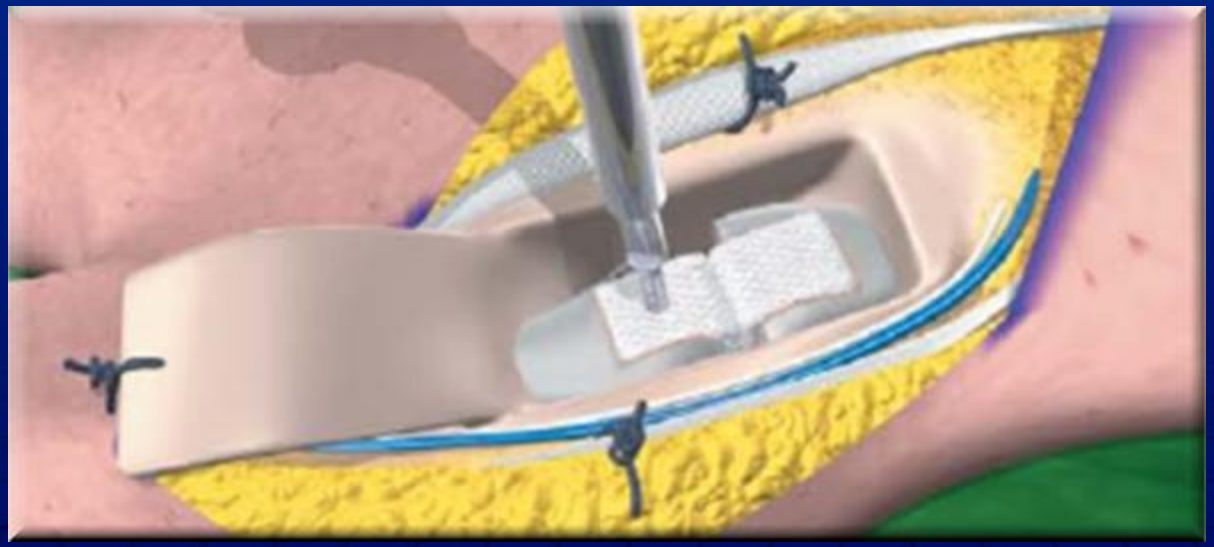
Artelon CMC Spacer – Surgical Technique

- Measure the depths for accurate choice of screw length and then tighten the screws



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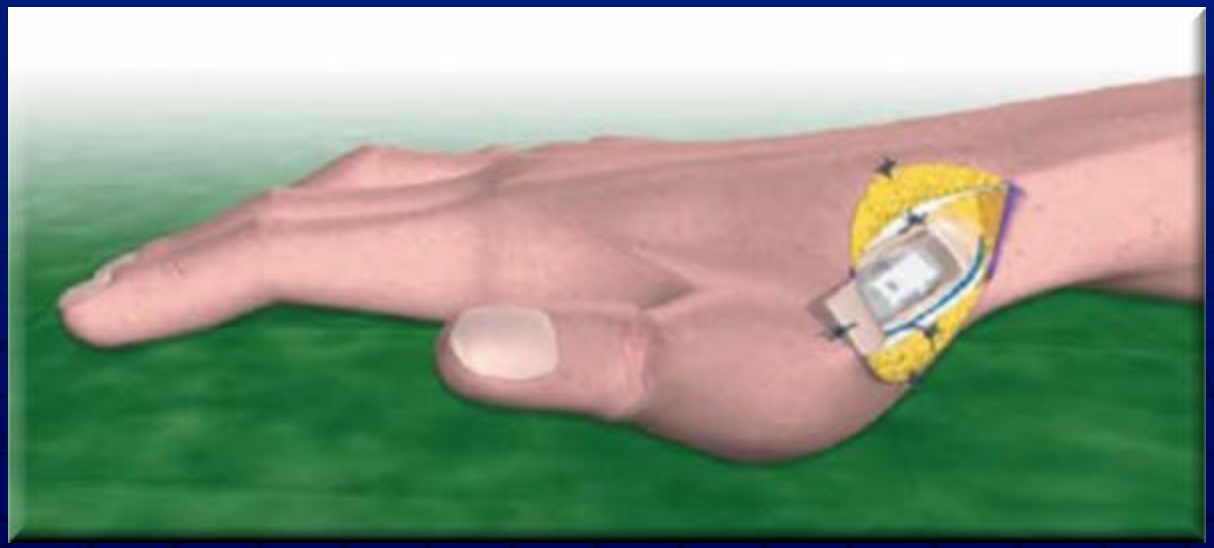
Artelon CMC Spacer – Surgical Technique

- Fix the thumb dorsally and drill, measure and tighten the screw
- It is important to reposition any subluxation of the joint



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Artelon CMC Spacer – Surgical Technique

- Be sure that stable bi-cortical fixation has been achieved

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Artelon CMC Spacer – Surgical Technique

- After Artelon CMC Spacer has been fixed in place, the periosteal flap is sutured back, and the incision in the skin is closed

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Artelon CMC Spacer – Surgical Technique

- The thumb is immobilized at 30° volar and radial abduction using a plaster bandage which must be changed after 2 -3 weeks. At this time, the IP joint of the thumb will not be covered by the cast.

Total immobilization time should be at least 5-6 weeks

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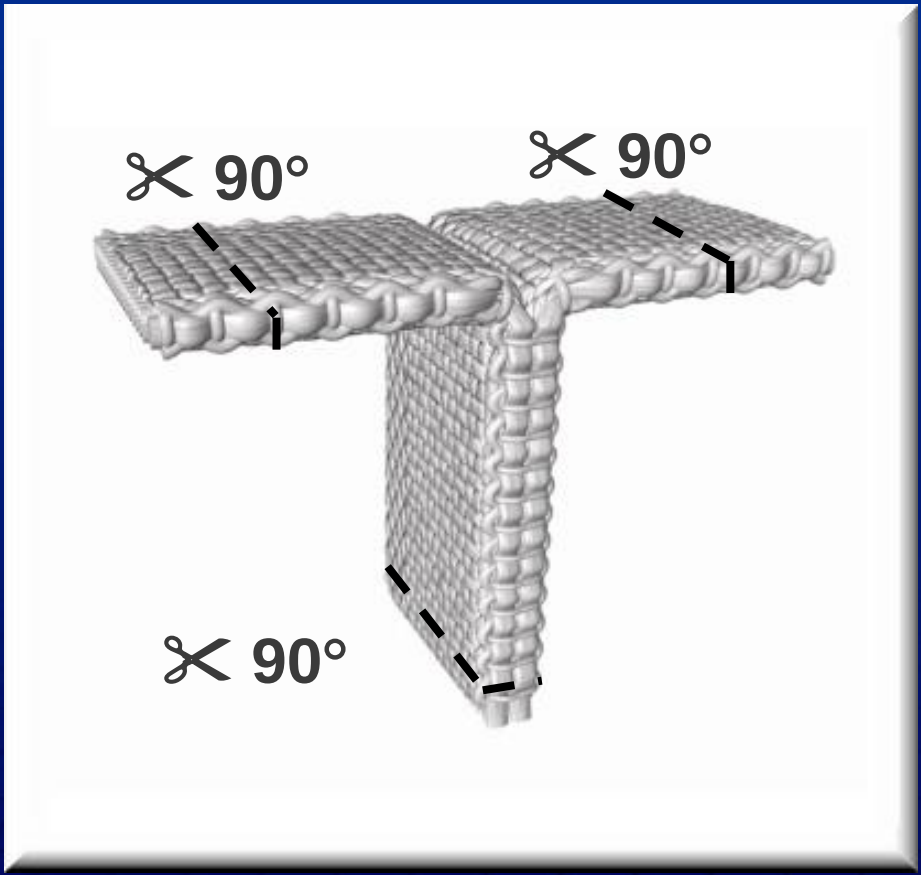
Artelon CMC Spacer – Trimming



- Both the “wings” and the interposition portion can be trimmed to fit to patient’s anatomy
- DO NOT adjust the width of wings or interposition portion

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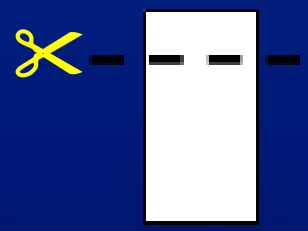
Trimming

OK



WRONG

WRONG

WRONG

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Artelon® CMC Spacer

Post Op

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Artelon CMC Spacer – Rehabilitation

- After 5-6 weeks of immobilization in plaster cast, rehabilitation shall be performed according to the routine practice of the surgeon
- Full weight bearing is allowed earliest after about 12 weeks of rehabilitation

Artelon® CMC Spacer

Clinical Experience

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Swedish Pilot Study Patients

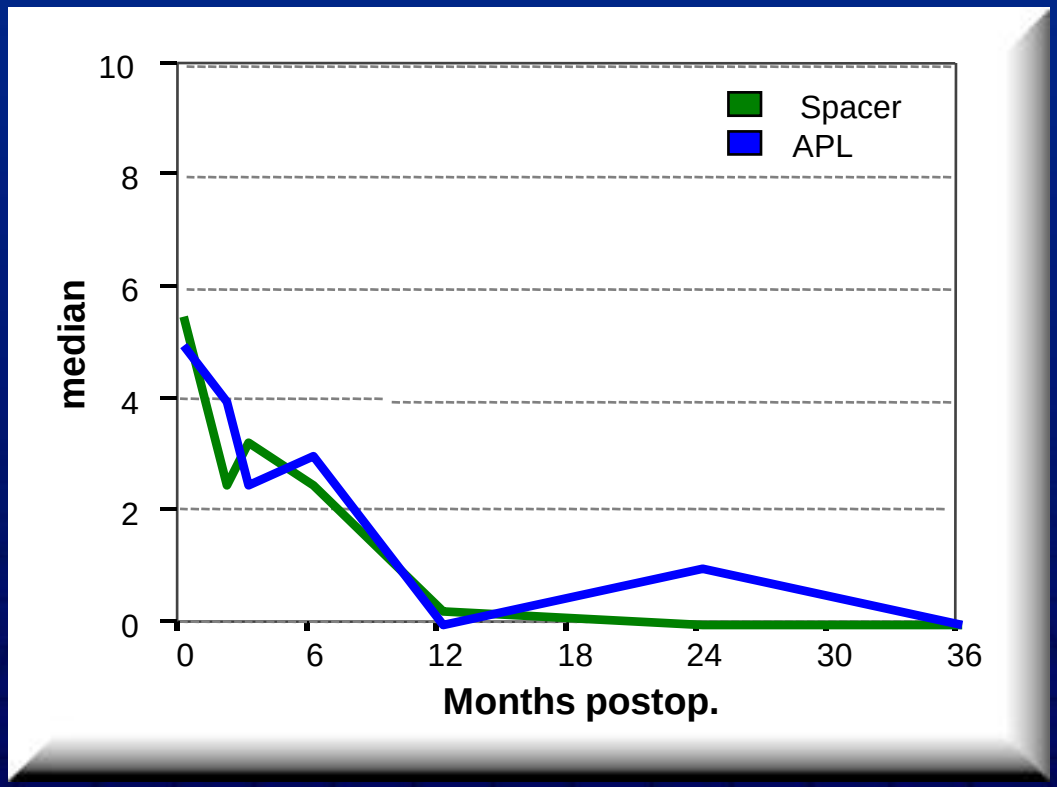
Table 1. Patients and Study Results

Patient	Group	Gender	Dominant Hand	Operated Hand	Follow-Up Time	Age	Pain (Visual Analog Scale)	
							Pre-operative	Post-operative
1	Spacer	F	R	R	3 y 3 mo	22	6.0	1.0
2	Spacer	F	R	R	3 y 8 mo	56	4.0	0
3	Spacer	F	R	L	3 y 6 mo	65	8.0	0
4	Spacer	F	R	R	3 y 4 mo	56	7.0	0
5	Spacer	M	R	R	3 y 4 mo	48	1.0	0
6	Spacer	F	R	R	2 y 8 mo	65	5.0	0
7	Spacer	F	R	L	2 y 7 mo	63	8.0	0
8	Spacer	F	R	L	2 y 8 mo	66	2.0	0
9	Spacer	F	L	R	2 y 8 mo	59	0	3.0
10	Spacer	F	R	R	2 y 8 mo	61	8.0	0
11	APL	F	R	L	3 y 2 mo	72	5.0	0
12	APL	F	R	L	1 y 10 mo	58	3.0	4.0
13	APL	F	R	R	3 y 1 mo	51	3.0	0
14	APL	F	R	R	3 y 2 mo	72	5.0	0
15	APL	F	R	R	3 y	59	8.0	2.0
Spacer	Median				3 y	60	5.5	0
	Minimum/maximum				2 y 7 mo/3 y 8 mo	22/66	0/8.0	0/3.0
APL	Median				3 y 1 mo	59	5.0	0
	Minimum/maximum				1 y 10 mo/3 y 2 mo	51/72	3.0/8.0	0/4.0
							—	—

Nilsson, A et. al Journal of Hand Surgery, March 2005

Swedish Pilot Study (3-yrs)

- Pain Index (according to VAS)



Nilsson, A et. al Journal of Hand Surgery, March 2005

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Independent Observations

Table 1. Continued

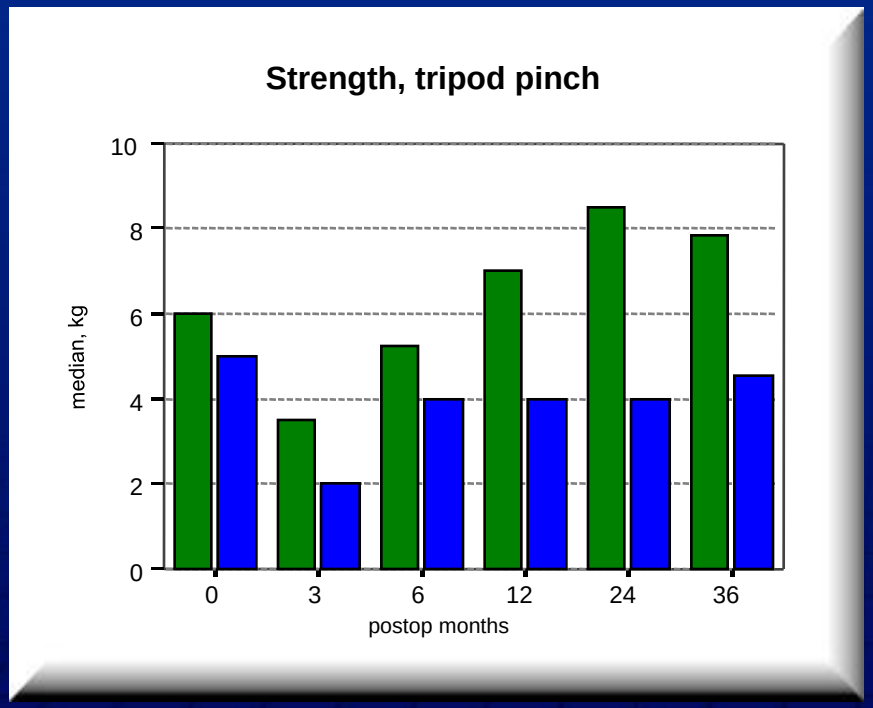
Key pinch (kg)		Tripod pinch (kg)		Transverse volar grip (kg)		Radial Range of Motion (°)		Volar Range of Motion (°)	
Pre-operative	Post-operative	Pre-operative	Post-operative	Pre-operative	Post-operative	Pre-operative	Post-operative	Pre-operative	Post-operative
7.0	8.5	6.5	7.0	16.0	40.0	25	30	30	20
7.5	8.0	6.0	10.0	14.0	30.0	20	10	20	6
5.0	6.0	4.0	7.5	33.0	31.0	35	35	60	20
2.5	8.0	3.0	10.0	12.0	30.0	50	20	35	10
12.0	10.5	10.0	8.0	50.0	50.0	45	35	30	20
7.0	8.0	7.0	9.0	29.0	30.0	20	25	12	20
5.5	6.0	6.0	6.0	22.0	28.0	30	32	30	20
7.5	8.0	6.0	6.0	22.0	26.0	18	30	20	30
4.0	2.0	4.0	2.0	14.0	8.0	20	40	20	20
4.0	8.0	4.0	8.0	24.0	31.0	20	18	18	20
4.5	6.0	4.0	4.0	22.0	20.0	15	15	40	14
2.5	3.5	3.5	2.0	18.0	20.0	40	20	30	15
9.0	7.0	9.0	8.0	28.0	33.5	22	35	20	20
6.0	5.0	5.0	4.0	30.0	27.5	30	25	42	25
7.0	5.0	6.5	4.0	22.0	20.0	20	25	20	15
6.2	8.0	6.0	7.8	22.0	30	22.5	30	25	20
2.5/12.0	2.0/10.5	3.0/10.0	2.0/10.0	12.0/50.0	8.0/50.0	18/50	10/40	12/60	6/30
6.0	5.0	5.0	4.0	22.0	20.0	22	25	30	15
2.5/9.0	3.5/7.0	3.5/9.0	2.0/8.0	18.0/30.0	20.0/33.5	15/40	15/35	20/42	14/25
—	$p \leq .05$	—	$p \leq .05$	—	—	—	—	—	—

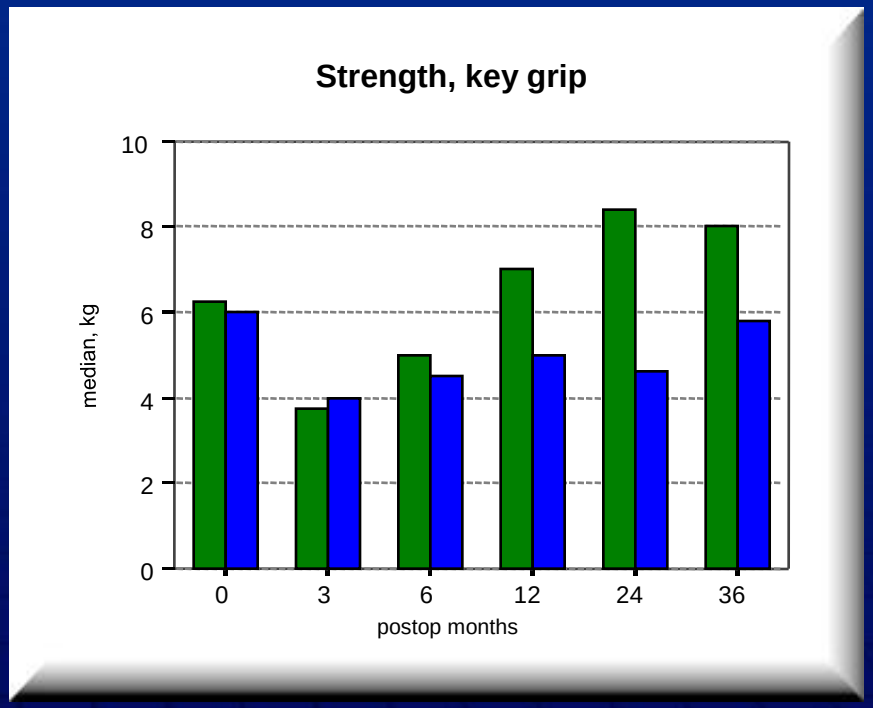
Pain (visual analogue scale) was recorded at maximal loading of key grip. Patient 9 displayed pain only in tripod pinch (5.0).

Nilsson, A et. al Journal of Hand Surgery, March 2005

Swedish Pilot Study (3-yrs)

- Strength





Spacer APL

Nilsson, A et. al Journal of Hand Surgery, March 2005

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ROM & Joint Stability

- **Range of motion was comparable** despite the Artelon® reinforcement producing a firm fixation between the metacarpal base and trapezium
- There was no difference between the groups regarding palmar adduction and abduction

Nilsson, A et. al Journal of Hand Surgery, March 2005

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Artelon® CMC Spacer
Pilot Study Conclusions

- Significant Increase In Pinch Strength
- Provides Comparable Pain Relief to LRTI
- Shows Histological Evidence of Close Contact Between Both Soft and Hard Tissue and Artelon

Nilsson, A et. al Journal of Hand Surgery, March 2005

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Artelon Experience

- Experiences of The Artelon CMC-I Spacer Based on:
  - 15 patient, pilot clinical trial with three year follow up (Nilsson, Journal of Hand Surgery, March 2005)
  - 109 patient Swedish multi-center trial with one year follow up
  - Over 3,500 patients in clinical practice

Swedish Multi-Center Trial Findings

- Pinch strength and stability is better with the Artelon spacer than with APL arthroplasty when measured one year post-surgery and onwards
- Pain relief is often faster with APL arthroplasty, while pain relief with the Artelon CMC spacer starts later and pain gradually decreases from 3 months post-surgery and onwards as the healing process continues. It is important that patients are informed about the relative slow onset of pain relief. This is a price they pay to achieve better long-term strength and stability
- Surgery with the CMC spacer (and the STT-spacer) is tissue-preserving and in case the patient is not satisfied with the results other surgical methods (such as APL arthroplasty) may be used later on. Resection of the trapezium results in grossly altered anatomy with subsequent shortening of the thumb and decreased pinch strength

B. Furberg, M.D.,PhD. VP Medical Affairs, Artimplant AB

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Swedish Multi-Center Trial Findings

- For patients with a combination of arthrosis in the CMC and the STT joints a spacer only in the CMC joint may not offer pain relief. Patients with combined osteoarthritis should be offered an Artelon spacer in each of the two joints or APL arthroplasty in which trapezium is removed and thus both the osteoarthritic joints
- Use of the Artelon CMC spacer is not recommended in patients with advanced osteoarthritis of the CMC-I joint (more than Eaton grade II-III). However, the outcome of surgery also depends on factors other than the extent of osteoarthritis. Thus, the results of surgery are often less favorable in patients with marked instability/subluxation of the joint and in those with long duration of inactivity before the surgery
- Artelon CMC spacer has been shown to be a better alternative when strength and stability is of significance. This is probably more often the case when the dominant hand is affected

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Swedish Multi-Center Trial Findings

- Good fixation of the wings of the CMC spacer is crucial. To achieve this, it is important that the cortical bone of the trapezium is only roughened not removed (see modified Instructions for use)
- Use of antibiotics is recommended as in other surgical procedures with implants in joints
- Postoperative immobilization for 6 weeks is needed to achieve good fixation of the spacer
- Remaining pain six months or more after surgery is often caused by concomitant arthrosis of the STT joint or by problems with the fixation of the spacer such as osteolysis around screws that are only fixed at the tip and thus moving. In such cases, removal of the screws (and not the spacer) has often given pain relief

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Histological Results

Histological analyses of 26 spacers explanted after 3-23 months have shown close contact between Artelon fibers and bone without intervening structures, chronic inflammatory cells or foreign-body response

However, in some cases there has been an inflammatory reaction in the soft tissue surrounding the wings probably due to insufficient fixation

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Artelon - Insufficient Fixation / Screw Removal

- Cortical bone screws have been removed in five reported cases (at 4 hospitals in Sweden)
  - All five cases were 6-12 months following the original Artelon implantation
- Reported symptoms include:
  - Pain, Redness, Swelling, etc. that does not subside for 4-6 months from the date of the original surgery
  - Osteolysis (bone loss) beneath the screw head or along the shaft of the screw had been observed on x-ray in all five cases

These types of symptoms can easily be interpreted to be “synovitis” or “foreign body reactions”

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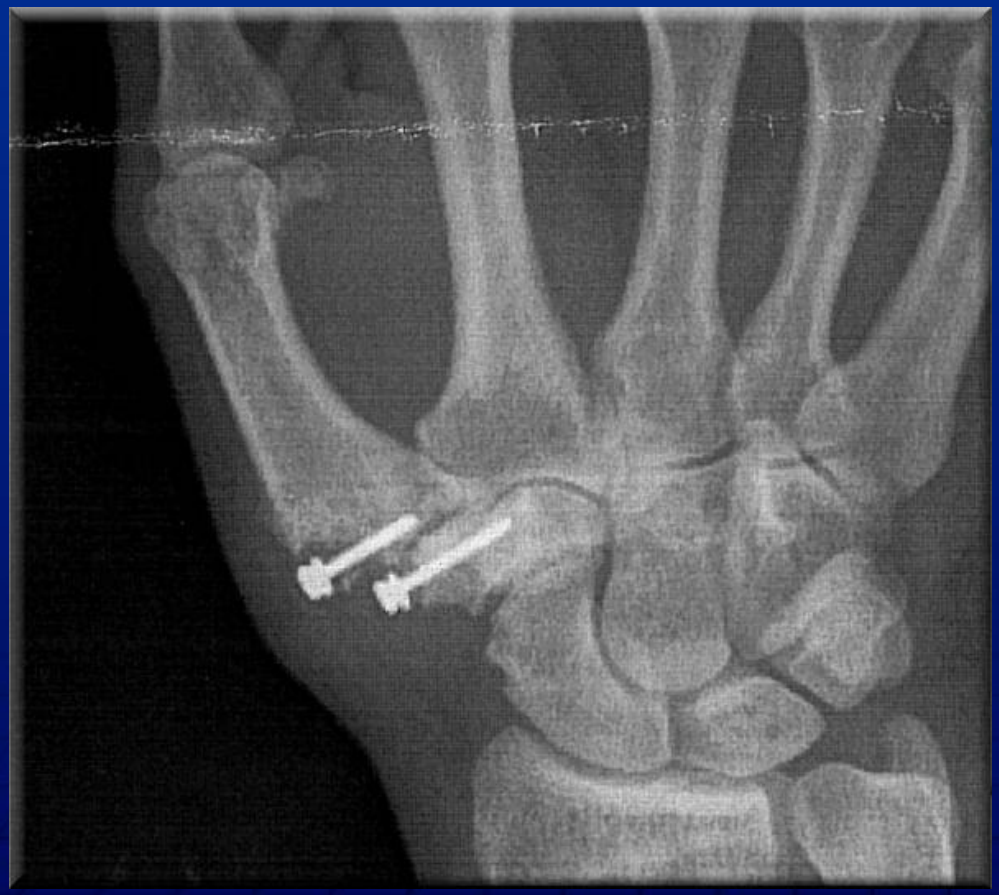
X-ray Taken 7 mths Post-op



- Patient complained of:
  - Pain
  - Redness
  - Swelling

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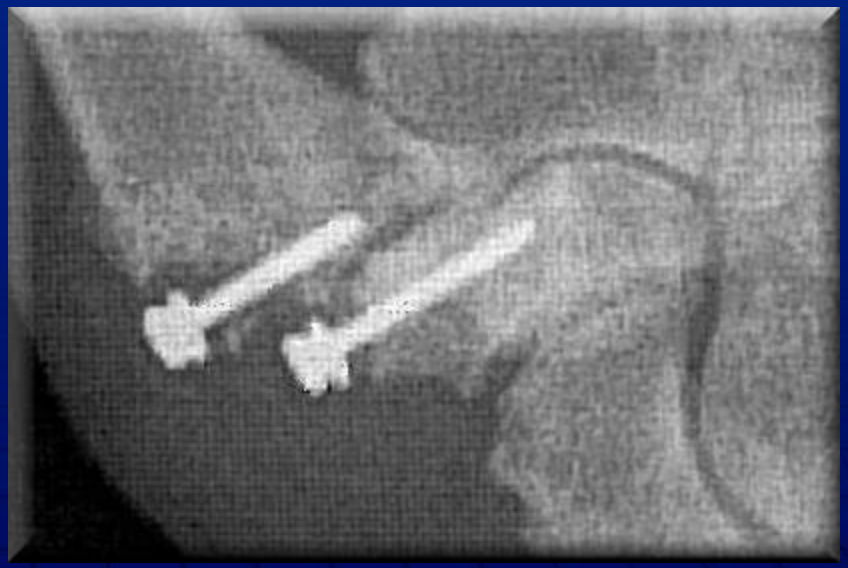
Importance of Secure Fixation

Cause was determined to be insufficient fixation due to:

- Good cortical contact on volar side
- Screw head movement in soft, decorticated bone on dorsal side

- In Less Than Two Months After Screw Removal:

- Patient's pain & swelling had resolved



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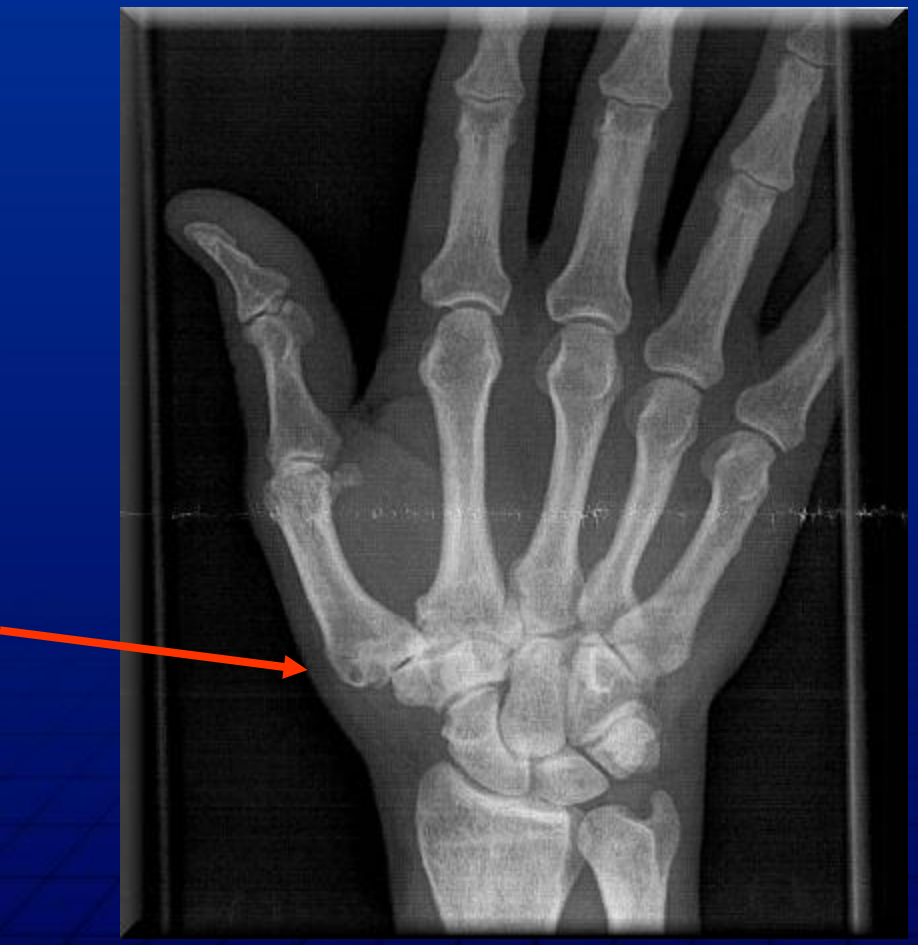
Artelon Issues
Insufficient Fixation / Screw Removal



Soft Tissue Irritation Due To Inadequate Fixation (loose screws) Appears To Be The Cause Of The Problems

- Following removal of the screws
  - All 5 patients have become pain free within 3-4 weeks
- X-rays were taken 3-4 months after removal in 3/5 patients
  - In all three cases, new bone formation was observed in the area where the osteolysis had been seen.

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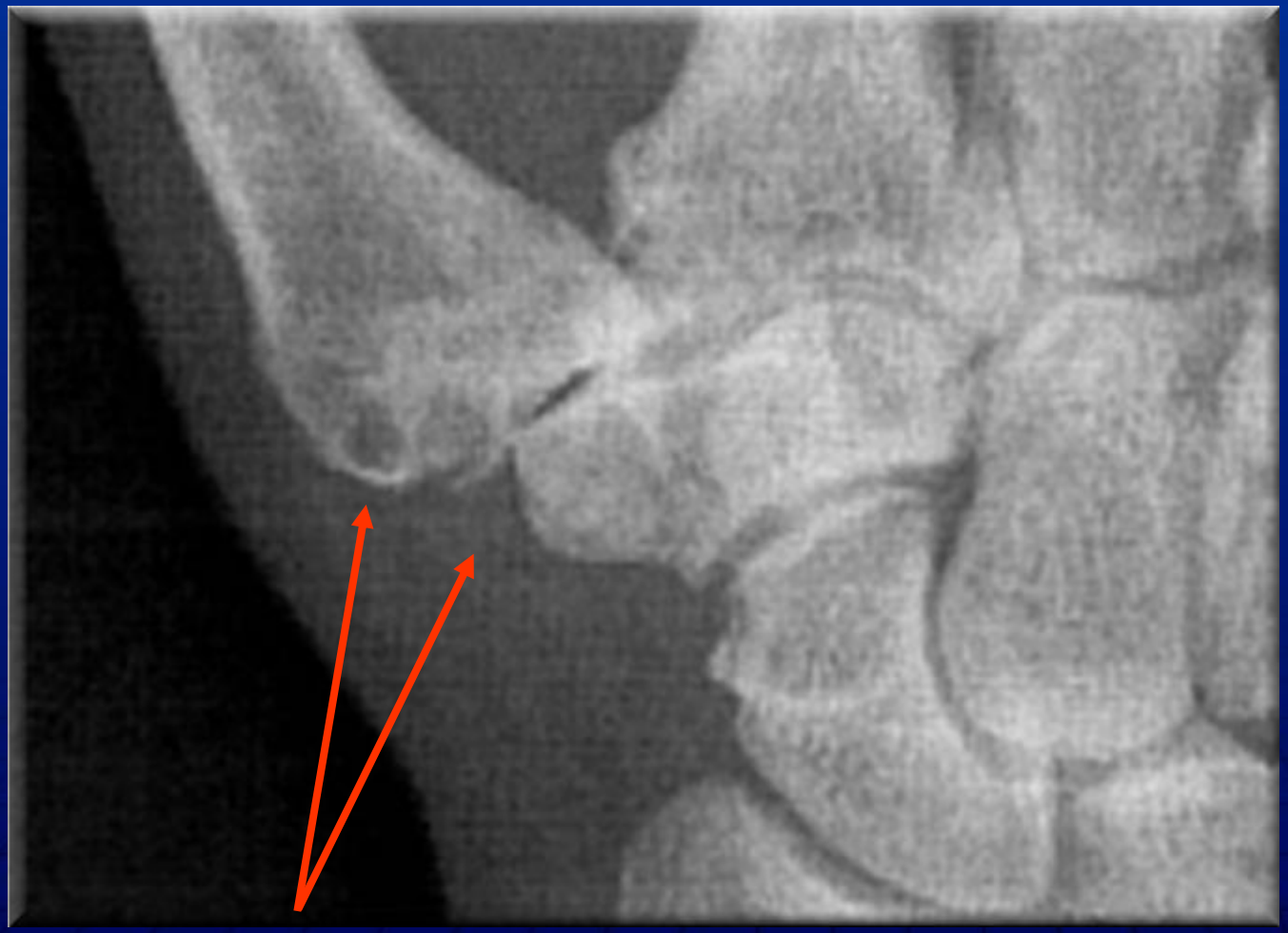
Artelon Screw Removal



X-rays were taken 3-4 months after removal in 3/5 patients

In all three cases, new bone formation was observed in the area where the osteolysis had been seen.

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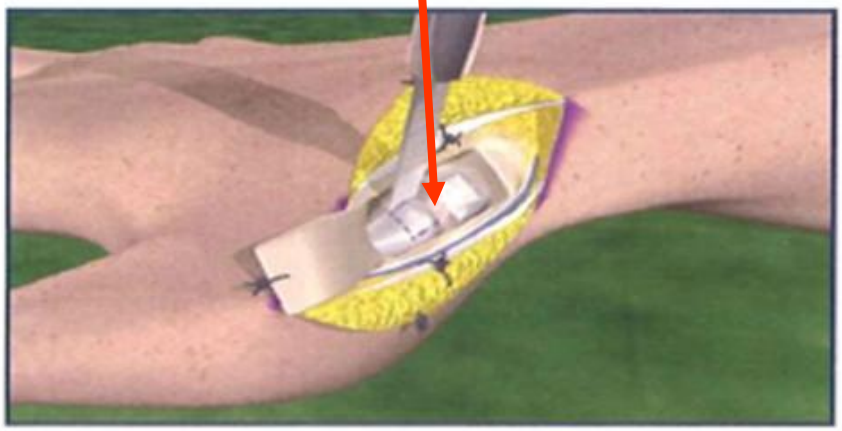
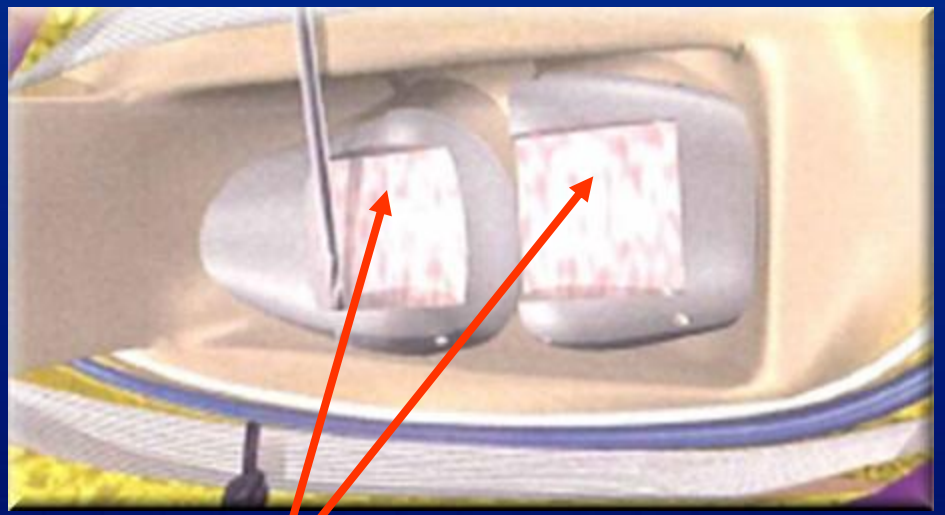
Artelon - Surgical Technique Changes

Old Method

Recommended that an osteotome be used to remove the cortical bone.



8. Remove the cortical bone in the marked area to make space for the wings of ARTELON Spacer CMC-I and to get bleeding surfaces.



Shows all the cortical bone has been removed on the dorsal surface which could result in micro-motion of screws or anchors that are deployed in soft cancellous bone

Artelon - Surgical Technique Changes

New Method

8. Flatten the cortical bone in the marked area with a burr to create a bleeding surface.
Note: Remove only enough cortical bone to achieve a bleeding surface.

Refined method recommends that less cortical bone be removed to allow for secure fixation of screws and anchors

12.A ARTELON CMC Spacer is fixated.
Note: Be sure that stable, bi-cortical fixation has been achieved

New note added to stress the need to achieve stable, bi-cortical fixation of screws

Artelon® CMC Spacer

Clinical Studies

- Retrospective Clinical Study
  - Completed August 2007
  - 74 thumbs in 73 patients
  - Paper submitted for publication to JHS
- Prospective Study
  - Hospital for Special Surgery, NYC
- Prospective Multi-Center U.S. Study
  - 12 centers

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Artelon® CMC Spacer

Clinical Studies

- Swedish Pilot Study
  - Paper published in March 2005 JHS
  - 6 year results pending
- Swedish Multi-Center Prospective Study

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Which Therapy Is Really More Conservative?

	Artelon	LRTI
Less Invasive	1 incision	2 incisions
Preserves Tissue	• Minimal (1-2 mm) resection of trapezium • Spares Tendon	• Excision of most or all of trapezium • Harvest of tendon
Relieves Pain	Good Pain Relief	Good Pain Relief
Restores Function	• Better Pinch Strength • Improved ROM	• Decreased Pinch Strength
Restores Form	• Preserves Normal Anatomy	• Shortening Of Thumb
Patient Satisfaction	• High Patient Satisfaction • Less invasive, good results	• More radical procedure • Unnecessary tissue destruction

Avanta CMC - I Implant

An Excellent Option For Elderly, Low Demand Patients

- Designed by Richard M. Braun, M.D. (San Diego, CA)
- Originally marketed by Sutter/ Techmedica
- Developed as a joint replacement of the trapeziometacarpal joint in cases of trauma, inflammatory, or degenerative disease
- First implanted in 1974, and currently in use world wide in various forms

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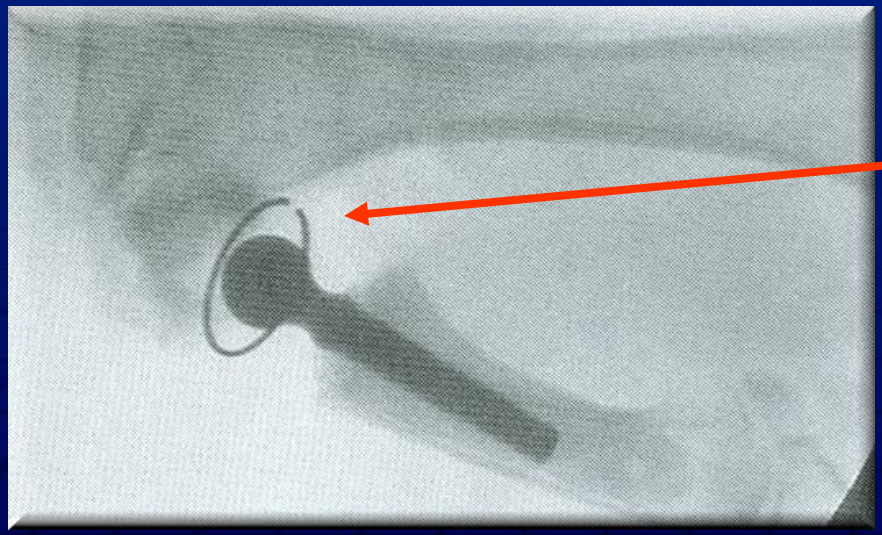
Avanta CMC - I Implant



- Trapezial Component
  - Cemented device requiring burring of the trapezium
  - Ridges assist with cement fixation
  - UHMWPE incorporates an x-ray marker

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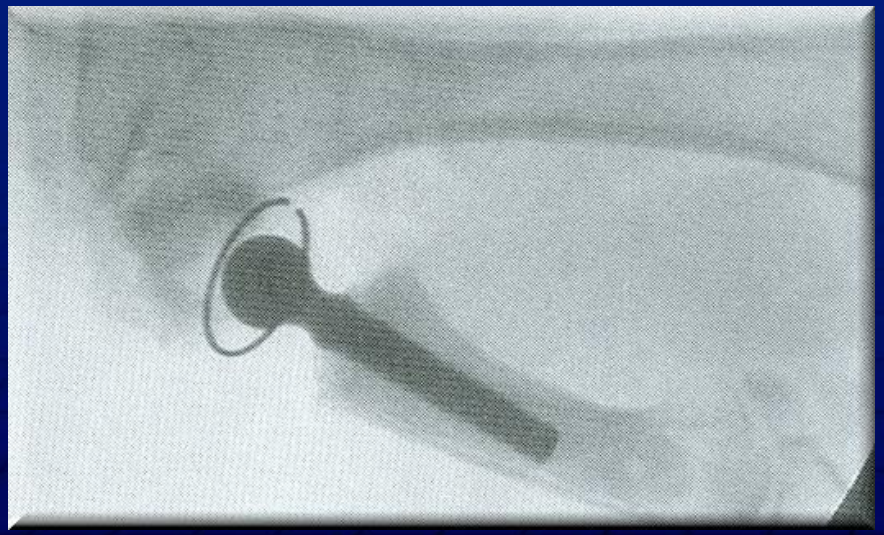
Avanta CMC - I Implant



- Metacarpal Component
  - Cemented device requiring resection of the metacarpal
  - Tapered ridge design enhances intermedualIry canal fit and cement fixation
  - Snap fit with the trapezial component
  - Dedicated instrumentation for placement of both components

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Artelon CMC Spacer

THANK YOU!

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