Artelon® CMC Spacer

The Artelon resurfacing concept is a tissue-preserving method for the treatment of osteoarthritis.
Artelon® CMC Spacer

Disease States
Thumb CMC Joint Arthritis

The most common surgically reconstructed area in arm due to OA
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
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)
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

Thumb Carpometacarpal Joint Arthritis – Dr. James Mahoney – St. Michael’s Hospital

Small Bone Innovations
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”
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
Artelon® CMC Spacer

Material / Technology
Versatility of Artelon®

- Scaffold
- Fiber
- Non-woven
- Granules
- Film

Textile processing
Artelon Applications

Joint Resurfacing

Ligament Reinforcement

Soft Tissue Replenishment

Tendon Reinforcement
**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.
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®

- 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
Artelon® Degradation

Polycaprolactone Degrades (~50%)

Urethane Urea Remains (~50%)

Degrades by hydrolysis –
Not affected by enzymes

Degradation completed after ~6 years

+ water
Similar profiles indicate that the only degradation process is hydrolysis.
~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.

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

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

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

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

Toluidine blue stain, 6 months after implantation – Artelon CMC Spacer
Artelon Biocompatibility In Soft Tissue

Artelon in close contact with collagen II expressed by chondrocytes

Indicates close, irritation-free incorporation with cartilage

Safranin-O stain, 3 months after implantation
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
61 months after implantation, the degraded Artelon is well incorporated in human ligament tissue.
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
Artelon® Sizes

Standard & Large Artelon

Artelon® CMC Spacer

Artelon® CMC Spacer LG
New Products In The Artelon Spacer Family

CMC LG  Arthro  STT

DRU*  MTP*

* Not Available For Sale in the U.S.
Arteloner Sizes

Arteloner® CMC Spacer Arthro

<table>
<thead>
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<th>Arteloner CMC Spacer Arthroscopic</th>
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<tbody>
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<td>Wing Length (B)</td>
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<td>Wing Width (B)</td>
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<td>Vertical Length (A)</td>
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Artelon Sizes

Artelon® STT Spacer

Artelon® STT Dimensions

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<td>Vertical Length (A)</td>
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<td>Vertical Width (A)</td>
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</table>
Artelon® CMC Spacer

Patient Selection
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 subluxation 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 subluxation 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.
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
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
Artelon® CMC Spacer

Surgical Technique
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
Artelon CMC Spacer – Fixation

Secure fixation is critical to procedural success

- Typical Fixation Techniques
  - Sutures
  - Suture Anchors (most common method)
  - Screws
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.
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
Note: Be sure that stable, bi-cortical fixation has been achieved
Artelon CMC Spacer – 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.
Artelon CMC Spacer – Surgical Technique

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

- Open the CMC-I joint with a dorsal incision
Artelon CMC Spacer – Surgical Technique

- Dissect a periosteal flap from the trapezial bone including the joint capsule
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
Artelon CMC Spacer – Surgical Technique

- Flatten the dorsal cortical bone in the marked area with a burr to create a bleeding surface.
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.
Artelon CMC Spacer – Surgical Technique

• Measure the depths for accurate choice of screw length and then tighten the screws
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
Artelon CMC Spacer – Surgical Technique

• Be sure that stable bi-cortical fixation has been achieved
After Artelon CMC Spacer has been fixed in place, the periosteal flap is sutured back, and the incision in the skin is closed.
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
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
Trimming

OK

WRONG

WRONG

WRONG
Artelon® CMC Spacer

Post Op
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
## Table 1. Patients and Study Results

<table>
<thead>
<tr>
<th>Patient</th>
<th>Group</th>
<th>Gender</th>
<th>Dominant Hand</th>
<th>Operated Hand</th>
<th>Follow-Up Time</th>
<th>Age</th>
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<tr>
<td>1</td>
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<td>F</td>
<td>R</td>
<td>R</td>
<td>3 y 3 mo</td>
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<td>R</td>
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<td>R</td>
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<td>5</td>
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<td>M</td>
<td>R</td>
<td>R</td>
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<td>48</td>
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<tr>
<td>6</td>
<td>Spacer</td>
<td>F</td>
<td>R</td>
<td>R</td>
<td>2 y 8 mo</td>
<td>65</td>
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<tr>
<td>7</td>
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<td>R</td>
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<td>59</td>
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<tr>
<td>Minimum/maximum</td>
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<td></td>
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<td></td>
<td>1 y 10 mo/3 y 2 mo</td>
<td>51/72</td>
<td>3.0/8.0</td>
<td>0/4.0</td>
</tr>
</tbody>
</table>

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
### Table 1. Continued

<table>
<thead>
<tr>
<th>Key pinch (kg)</th>
<th>Tripod pinch (kg)</th>
<th>Transverse volar grip (kg)</th>
<th>Radial Range of Motion (°)</th>
<th>Volar Range of Motion (°)</th>
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</tr>
</tbody>
</table>

Pain (visual analogue scale) was recorded at maximal loading of key grip. Patient 9 displayed pain only in tripod pinch (5.0).
Swedish Pilot Study (3-yrs)

- **Strength**

![Strength, tripod pinch graph]

![Strength, key grip graph]

Nilsson, A et. al  *Journal of Hand Surgery, March 2005*
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.
• 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
Artelon Experience

- Experiences of The Artelon CMC-I Spacer Based on:
  - 109 patient Swedish multi-center trial with one year follow up
  - Over 3,500 patients in clinical practice

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

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

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

B. Furberg, M.D., PhD. VP Medical Affairs, Artimplant AB
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”
X-ray Taken 7 mths Post-op

• Patient complained of:
  – Pain
  – Redness
  – Swelling
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
Artelon Issues
Insufficient Fixation / Screw Removal

- 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.

Soft Tissue Irritation Due To Inadequate Fixation (loose screws) Appears To Be The Cause Of The Problems
In all three cases, new bone formation was observed in the area where the osteolysis had been seen.

X-rays were taken 3-4 months after removal in 3/5 patients.
Artelon - Surgical Technique Changes

Old Method

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

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.

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.
Artelon - Surgical Technique Changes

New Method

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

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

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.

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

Clinical Studies

• Swedish Pilot Study
  - Paper published in March 2005 JHS
  - 6 year results pending

• Swedish Multi-Center Prospective Study
## Which Therapy Is Really More Conservative?

<table>
<thead>
<tr>
<th></th>
<th>Artelon</th>
<th>LRTI</th>
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<tbody>
<tr>
<td><strong>Less Invasive</strong></td>
<td>1 incision</td>
<td>2 incisions</td>
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</table>
| **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
Avanta CMC - I Implant

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

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