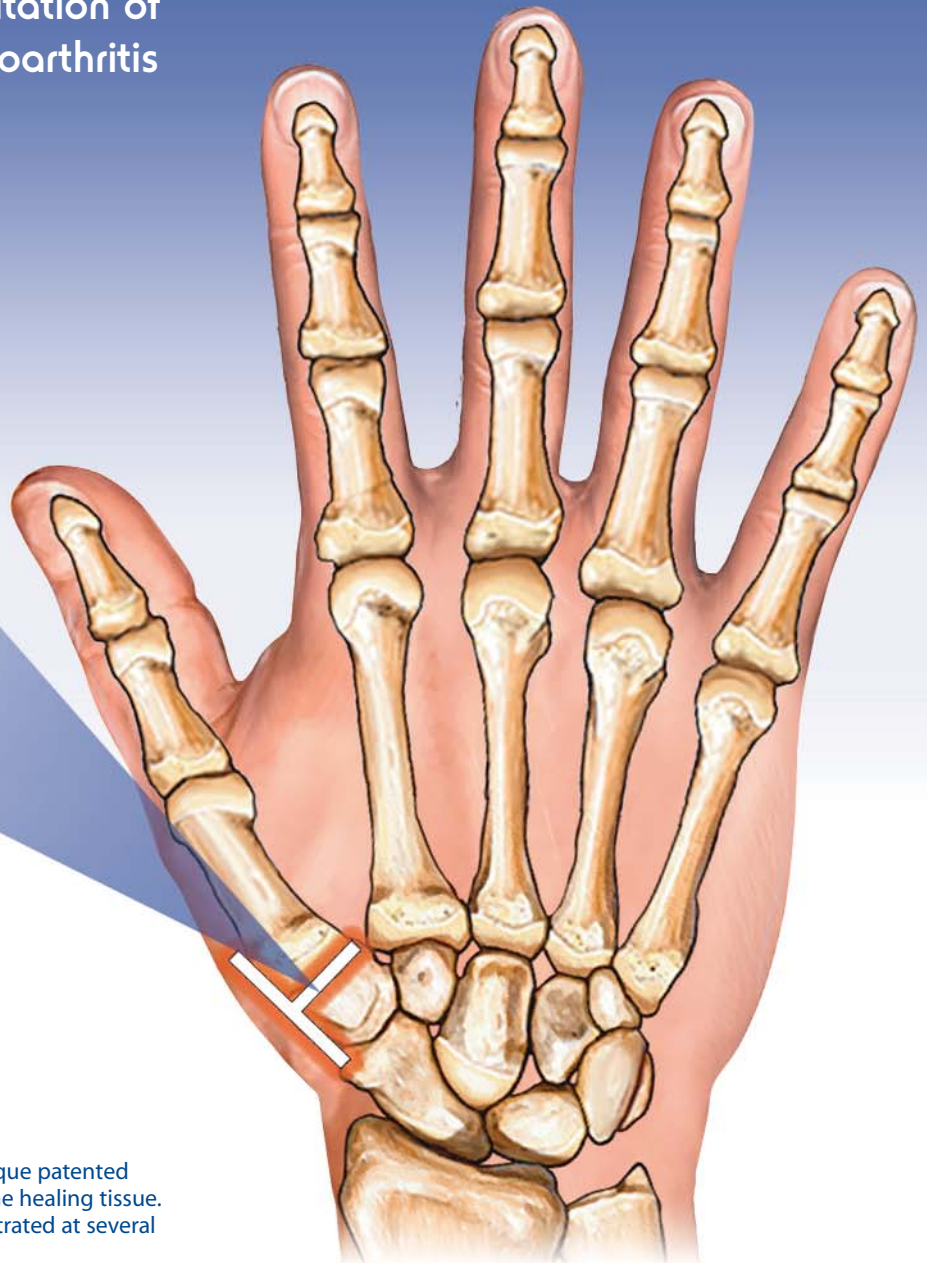


SBi

SMALL BONE INNOVATIONS, INC.

ARTELON[®] CMC SPACER SURGICAL PROCEDURE

Artelon[®] CMC Spacer adopts a biological and tissue preserving approach to the rehabilitation of patients with CMC-I osteoarthritis



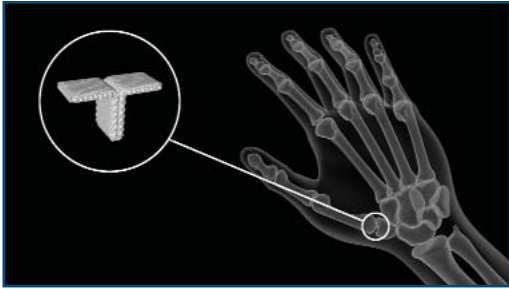
Distributed by:

Small Bone Innovations, Inc.
1380 South Pennsylvania Ave.
Morrisville, PA 19067
1-800-778-8837

Artelon[®], a degradable polyurethaneurea, is a unique patented biomaterial that acts as a temporary support to the healing tissue. Excellent biocompatibility for Artelon[®] is demonstrated at several time intervals in soft tissue and bone.

Artelon® CMC Spacer

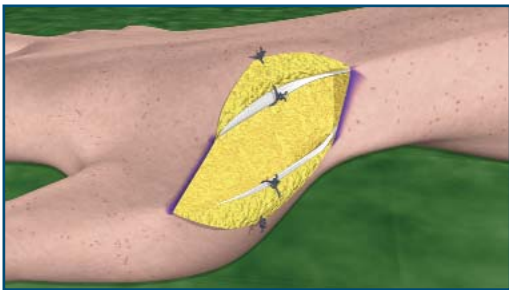
Surgical Procedure



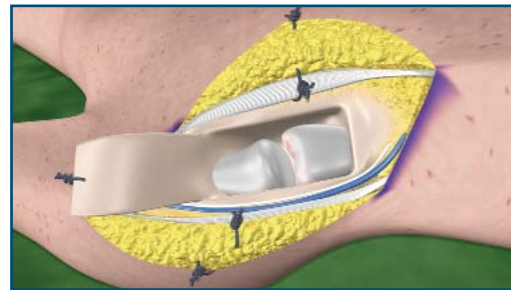
1. ARTELON® CMC Spacer is intended to be implanted into the first carpometacarpal joint (CMC-1) as an interpositional spacer between the trapezium bone and the first metacarpal bone.



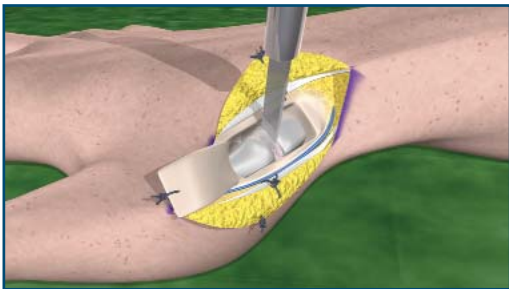
2. Soak ARTELON® CMC Spacer in sterile saline for at least 5 minutes before use.



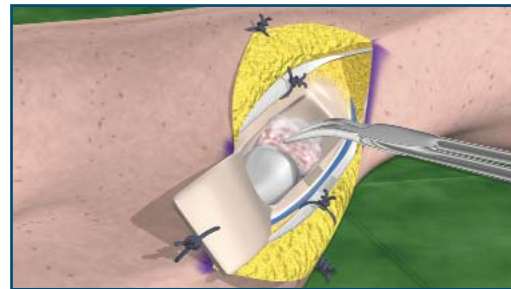
3. Open the CMC-1 joint with a dorsal incision.



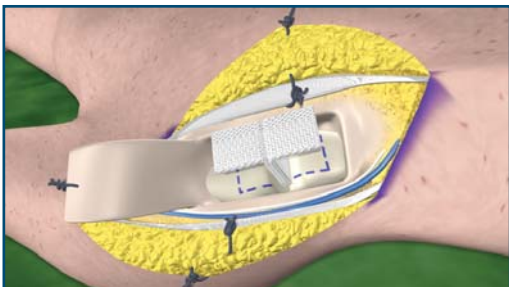
4. Dissect a periosteal flap from the trapezium bone including the joint capsule. Extend the flap to a total length of approximately 1-2cm. The illustration shows the flap being dissected in the distal direction, but a proximally based flap may be used as an alternative.



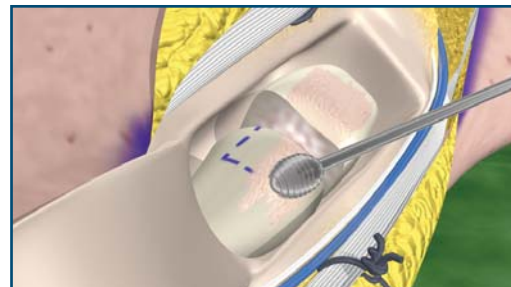
5. Resect the distal joint surface along with 1-2mm of the subcondral bone on the articular surface of the trapezium bone. Leave the articular surface of metacarpal bone intact. **Note: It is essential to create a bleeding surface on the trapezium bone but to keep an intact surface on the metacarpal bone in order to create a new joint surface to articulate against.**



6. Remove osteophytes from the joint lines.



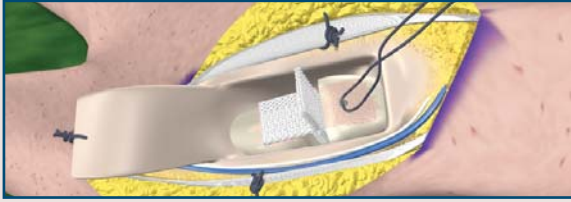
7. Mark the position of the wings.



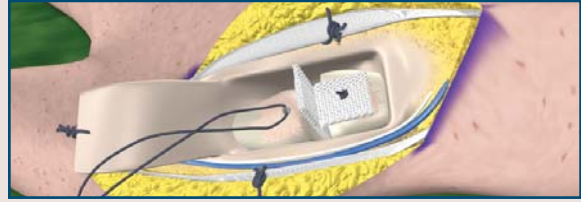
8. Flatten the cortical bone in the marked area with a burr to create a bleeding surface. **Note: Remove only enough cortical bone to achieve a bleeding surface.**

FIXATION WITH SUTURE ANCHORS

- If resorbable anchors are used, be sure that the anchor material will not degrade in less than six months.
- Do not use resorbable sutures to secure the wings.



9.A Center and deploy the suture anchor in the area beneath the wing of the spacer in the trapezium bone. Position the pre-soaked spacer in the joint. If necessary, the wings and interpositional spacer portion can be shortened by cutting at a 90 degree angle.

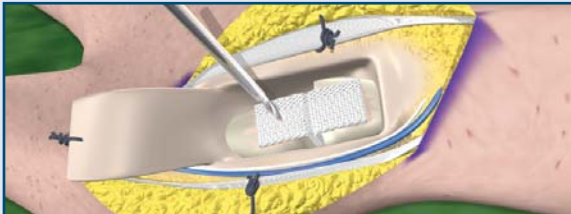


10.A While pressing the interposition portion of the spacer against the bleeding surface of the trapezium bone, securely suture through the middle of the wing, so that the wing fits firmly against the dorsal surface.



11.A Center and deploy a second suture anchor beneath the area of the spacer in the metacarpal bone. Fix the thumb dorsally; align the dorsal surface of the metacarpal and trapezium bones. Securely suture through the middle of the wing so that the wing fits firmly against the dorsal surface. Reposition any subluxation of the joint.

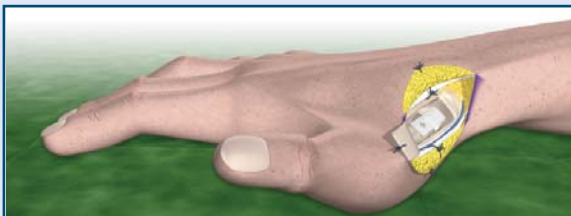
FIXATION WITH SCREWS



9.B Position the pre-soaked spacer into the joint. If necessary, the wings and interpositional spacer portion can be shortened by cutting at a 90 degree angle. Drill a screw pilot hole through the center of the wing using a sharp drill. Make sure to penetrate the volar cortical side of the metacarpal bone.



10.B Measure the depth for accurate choice of screw length. Use self-tapping titanium screws. Tighten the screw.



11.B Fix the thumb dorsally; align the dorsal surface of the metacarpal and trapezium bones. Drill, measure and tighten a screw into the trapezium bone. Reposition any subluxation of the joint.

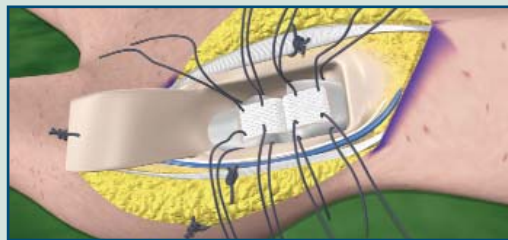


12.B Make sure that stable bicortical fixation has been achieved.

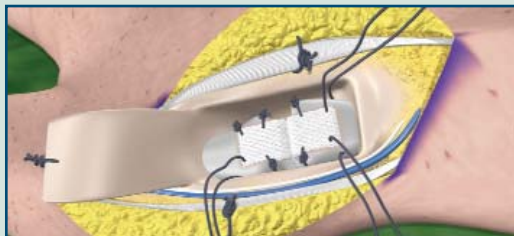
FIXATION WITH SUTURES



9.C Burr channels are drilled with a 1-1.2mm drill, preferably in each corner.



10.C Place the sutures (non-absorbable, 4-0 or 3-0) no closer than 2mm to the edges of the wings.



11.C Start to tie the knots from the joint.



12.C ARTELON® CMC Spacer is fixed.



13. Reattach the periosteal flap. Close the skin.



14. To avoid problems with the annular ligament it is important to keep the load exerted on the spacer to a minimum and to ensure that the MCP joint is not in hyperextension. Place a roll of wadding in the hand to keep the thumb in 10° flexion and immobilize the thumb at a 30° volar and radial abduction using a cast.

The cast must be changed and the stitches can be removed after 2-3 weeks. Cast with the IP joint free for the next 2-3 weeks. The total cast time must be at least 5 weeks.

The information contained in this technique guide was consistent with the package insert on the date the guide was printed. However the package insert may have been revised after that date. To obtain a current package insert, please contact Small Bone Innovations.

Caution: United States federal law restricts this device to sale by or on the order of a physician.

Artelon is a degradable polyurethaneurea,
Manufactured by Artimplant AB.
Artelon® is a registered trademark of Artimplant, AB.

Distributed in North America by:

Small Bone Innovations, Inc.
1380 South Pennsylvania Ave.
Morrisville, PA 19067
(215) 428-1791 / Fax (215) 428-1795
SBI Customer Service: (800) 778-8837
Technical Support: (866) SBI-TIPS
www.totalsmallbone.com
customerservice@totalsmallbone.com

7269 1M Copyright ©2008 Small Bone Innovations, Inc.
and Artimplant AB.
All rights reserved.

SBI
SMALL BONE INNOVATIONS, INC.

Distributed Worldwide by:

Small Bone Innovations International
ZA Les Bruyères - BP 28
01960 Péronnas, France
Tel: +33 (0) 474 21 58 19
Fax: +33 (0) 474 21 43 12

Manufactured & Distributed in Scandinavia by:

ARTIMPLANT AB
Hulda Mellgrens Gata 5
SE-421 32 Västra Frölunda Sweden
Tel: +46 31 746 56 00
Fax: +46 31 746 56 00

Artimplant Part # 1012880D
MKT 40110 Rev. E 11/08