



You are invited

to explore this new surgical technique for moderate bunion cases



Clinical results demonstrate:

This is the Ultimate Bunion Correction Solution

See inside for more information



AlphaMet
Orthopedics

Patient Friendly Bunion Surgery

A Minimally Invasive, Non Osteotomy Hallux Valgus Correction

CyclaPlex Correction System is a newly introduced implant device and surgical instruments intended for Hallux Valgus deformity correction. The CyclaPlex procedure corrects foot deformity without the need to perform bone osteotomy.

Post op healing and recovery are prompt. Immediate

weight bearing is permitted. Patients are enjoying faster back to normal life.



Restoring Foot Back to Normal Anatomy

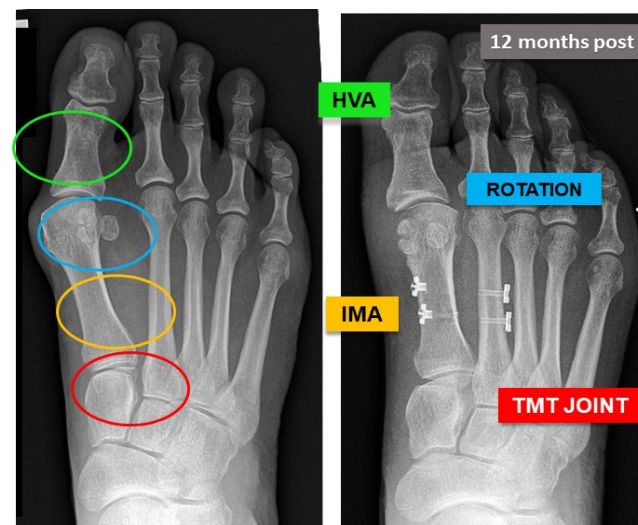
Surgical animation



Search :

CyclaPlex Correction System

We make it easier to the patient



1st Ray Correction

1st metatarsal deformity correction - The CyclaPlex procedure is based on a controlled pull of the 1st metatarsal back to its original, normal anatomical position. Correction is performed without Osteotomy. Potential complications such as Mal-union, Non union are avoided.

Pronation and elevation correction - as 1st metatarsal is pulled back it will naturally rotate back to its natural position. Sesamoids are re-balanced. 1st met elevatus is corrected.

No Fusion of 1st TMT Joint - 1st metatarsal is pulled back naturally and no osteotomy performed. Unnecessary, healthy, joint elimination is avoided. Risk of fusion complications is removed.

Long term reliability - bench testing had demonstrated long term durability and implant reliable functionality. Tested for 3 million jogging strides with perfect sutures at end of test. This is equivalent to 3 years of activity.

Prompt recovery - as osteotomy is not performed, post op protocol permits weight bearing. Clinical study follow ups show lower levels of pain back to normal within weeks.

We made it simple to the surgeon

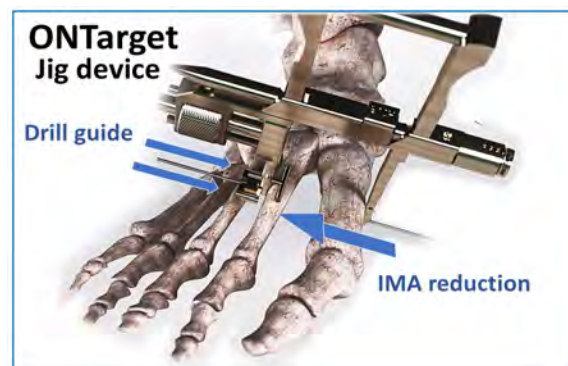
Minimally Invasive surgery

A unique surgical instrument makes the surgery procedure straight forward, very accurate and repeatable.

A unique jig instrument - ONTarget device - allows easy and controlled IMA reduction. IMA reduction is performed prior drilling the holes across the bones. The device has special drilling leads that facilitate accurate drilling directions and accurate placement of the two implants across 2nd and 1st metatarsals 10mm apart.

Configuration

- ❖ CyclaPlex Correction System comprises of two implant units that are implanted side by side.
- ❖ Single use drill bits and guide wires are provided in each set.

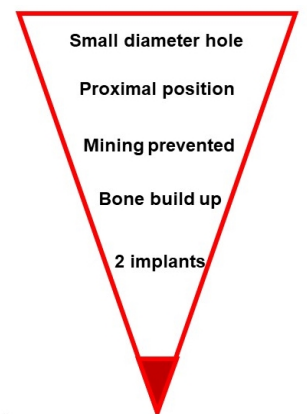


Accurate, parallel positioning of two implants

The CycloPlex solution advantage

Non osteotomy, Button and Suture techniques for Hallux Valgus deformity correction had been used in the past. However, high rate of 2nd metatarsal stress fracture were reported CycloPlex device has been specially designed to reduce the risk of 2nd metatarsal fracture .

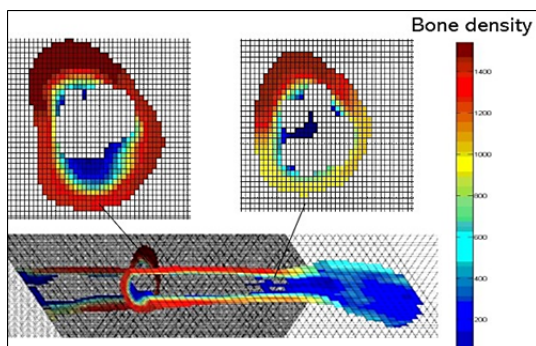
Fracture Risk Reduction



- The hole drilled in 2nd metatarsal is small diameter, only 1.8mm
- Implant position is proximal where bone is thicker and stronger compared to previous device distal position
- Two parallel implants share the load and distribute pressure
- Screw type design avoids suture mining into the bone during gate
- Screw type design from titanium material facilitates bone growth around the implant at the bone cavity strengthening the bone
- Periosteal reaction strengthens bone cortices

Residual risk is minimal

Proximal position-stronger bone

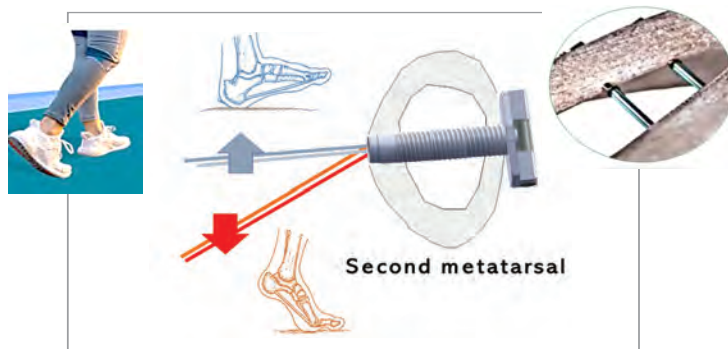


For long term durability and maintaining IMA for long term each implant has 4 Ultra High Molecular Weight polyethylene suture Each implant withstand forces of above 520 N or 110LB, this is in comparison to forces of about 8 LB between the metatarsals. Long term durability was tested on jogging simulator for 3 million cycles , equivalent for 3 years of activity. Post 3 million cycles sutures were examined for degradation and were found almost intact .



Preventing mining into the bone

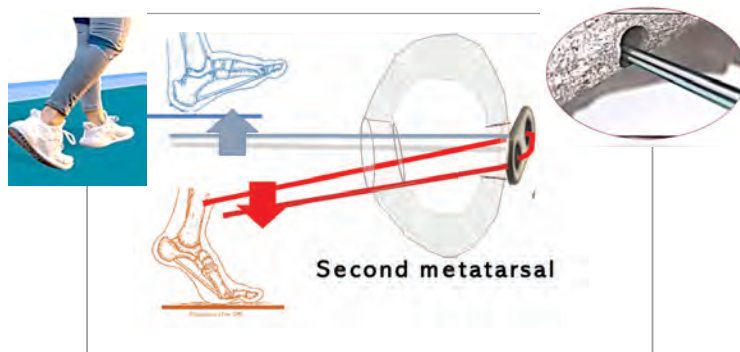
CycloPlex device - Bone is intact



This is in comparison to previous device structure where the suture has direct contact with the bone and is mining over time increasing the hole diameter , generally over 3-4 months

Regular Button and Suture device

Suture mines into the bone , hole increases



Based on clinical study results patients are expected to experience faster recovery

CyclaPlex Correction System



The Ultimate Bunion Correction Solution

- Minimally Invasive
- No osteotomy performed -sparing all associated complications
- Minimal intervention (only small holes in bones)
- TMT joint maintained and normalized (Non-Fusion)
- Repeatable and accurate procedure
- Reversible - No bridges burned
- Restores foot alignment back to normal anatomy (Cannot be achieved in osteotomy techniques)
- Restores foot mobility
- Corrects 1st metatarsal elevation
- Weight bearing post surgery- permitted
- Back to normal activity at a shorter time
- Lower pain levels post surgery

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