



Patient Risk Information

At Treace Medical, our mission is to assist foot and ankle surgeons in improving patient outcomes. We offer the patented Lapiplasty® 3D Bunion Correction™ system which surgeons may use to correct your bunion.

The decision to undertake surgery is one that is not to be taken lightly. Results of surgery will vary due to numerous factors. Not all patients are candidates for this product and/or procedure. Only your doctor can advise if Lapiplasty® 3D Bunion Correction™ is appropriate for your specific condition.

The information provided below, as well as throughout Lapiplasty.com, is available for your review in preparation for your consultation with a trained surgeon. We encourage you to read the information on the risks associated with the Lapiplasty® Procedure and discuss any questions you may have with your doctor so that you can make an informed decision as to whether Lapiplasty® 3D Bunion Correction™ is right for you.

What are the risks associated with the Lapiplasty® Procedure?⁽¹⁻⁴⁾

As with any medical treatment, individual results may vary. There are potential risks, and recovery times vary. Potential risks include but are not limited to:

- Infection
- Adverse reactions to a foreign body
- Loosening, bending, cracking, or fracture of the implants
- Loss of fixation of bone
- Delayed / loss of correction or loss of anatomic position with nonunion or malunion
 - Nonunion is when a fractured bone has been unable to heal
 - Malunion is when a fracture has healed in an abnormal or less than optimal position
- Migration of the implant or loosening of the implant
- Delayed correction in alignment of the bones
- Decrease in bone density
- Bursitis or inflammation of the bursa sac which provides cushion and aids in reducing friction between tissues
- Revision surgery or removal of the implants

You are not a candidate for the Lapiplasty® Procedure if the following applies:

- Pediatric patient aged less than 12 years of age
- Adolescent patients between 12-21 years of age where the implant will cross open growth plates in skeletally immature patients

As with any surgical procedure, you are not a candidate for surgery if any of the following apply:

- Active Infection
- Blood supply limitations, obesity, and insufficient quantity or quality of bone
- Mental or neurologic conditions preventing compliance with postoperative care instructions
- Known sensitivity to implantation of a foreign body or the implant materials
 - Where material sensitivity is suspected, testing is to be completed prior to implantation of the device

Please consult your surgeon if any of the above circumstances exist.

What are the postoperative care considerations with surgical implants?

Proper postoperative care in accordance with your surgeon's instructions is key to a successful recovery. As with any implant, there are limitations of the implant and failure to comply with prescribed physical activity instructions has been implicated in premature failure of similar devices. For further information on the recovery process, follow this link to Lapiplasty.com/recovery/. Please consult your surgeon for a full understanding the postoperative care associated with the Lapiplasty® Procedure.

References

1. Treace Medical Concepts Plating System Instructions for Use (LBL 1405-9005)
2. Treace Medical Concepts Compression Implant System (09-00005L)
3. Treace Medical Concepts Screw Fixation System Instructions for Use (LBL 1405-9056)
4. Treace Medical Concepts Snap-Off Screw System Instructions for Use (LBL 1405-9110)

Lapiplasty® is a surgical procedure. Only a surgeon can tell if Lapiplasty® procedure is right for you. As with any surgical treatment, there are risks; individual results may vary; and recovery takes time. Potential risks include infection, pain, implant loosening and loss of correction with improper bone healing. For more information on benefits, risks and recovery, visit Lapiplasty.com