Stryker Total Ankle Replacement

Important safety information

Intended use
Stryker's total ankle systems are intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications
Stryker total ankle systems are indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Stryker total ankle systems are additionally indicated for patients with a failed previous ankle surgery.

Caution
In the united states, the ankle prosthesis is intended for cement use only.

Contraindications
Contraindications include:
1) Osteomyelitis;
2) Insufficient bone stock or bone quality;
3) Infection at the ankle site or infections at distant sites that could migrate to the ankle;
4) Sepsis;
5) Vascular deficiency in the ankle joint;
6) Skeletally immature patients (patient is less than 21 years of age at the time of surgery);
7) Cases where there is inadequate neuromuscular status (e.g., Prior paralysis, fusion and/or inadequate abductor strength), poor skin coverage around the joint which would make the procedure unjustifiable;
8) Neuropathic joints;
9) Excessive loads as caused by activity or patient weight;
10) Patient pregnancy;
11) Severely compromised musculature or neuromuscular function.
12) Uncooperative patient or patient with neurologic disorders, incapable of following instructions

Warning
This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation. High levels of activity may increase the risk of adverse events. Surgeons should carefully consider the advisability of ankle replacement in patients with metabolic disorders or pharmacological treatments that impair bone formation or with conditions that may impede wound healing (e.d., end stage diabetes or malnutrition).

Adverse effects
1. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate matter. Particulate is generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue including third-body wear. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components.
2. Although rare, metal sensitivity reactions in patients following joint replacement have been reported. Implantation of foreign material in tissues can result in histological reactions involving production of macrophages and fibroblasts.
3. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma.
4. Dislocation and subluxation of prosthetic components can result from improper positioning and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions.
5. Prosthetic components can loosen or migrate due to trauma or loss of fixation.
6. Infection can lead to failure of the joint replacement.
7. While rare, fatigue fracture of the prosthetic component can occur as a result of trauma, strenuous activity, improper alignment, incomplete implant seating, or duration of service.
8. Bone damage or fracture may occur during installation due to compromised bone quality, osteoporosis, or previous bone injury or surgery.
9. Allergic reactions to the prosthetic component materials can occur.

Intraoperative and early postoperative complications can include:
1) Pain;
2) A sudden drop in blood pressure intra-operatively due to the use of bone cement;
3) Damage to blood vessels;
4) Temporary or permanent nerve damage resulting in pain or numbness of the affected limb;
5) Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction.
6) Hematoma;
7) Delayed would healing; and
8) deep wound infection (early or late) which may necessitate removal of the prosthesis. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required.

Late postoperative complications can include:
1) Pain;
2) Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
3) Periarticular calcification or ossification, with or without impediment to joint mobility; and
4) Inadequate range of motion due to improper selection or positioning of components or periarticular calcification.

Precautions
1. The patient must be advised of the limitations of the reconstruction and the need for protection of the prosthesis from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the joint replacement have been implicated with failure of the reconstruction by loosening, fracture and/or wear of the prosthetic components. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult.
2. The patient should be cautioned to limit activities and protect the replaced joint from unreasonable stresses, and follow the instructions of the physician with respect to follow-up care and treatment. The patient should be closely monitored if a change at the operative site has been detected. The possibility of deterioration of the joint should be evaluated and possible revision surgery considered.
3. The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the prosthesis does not replace normal healthy bone, that the prosthesis can break or become damaged as a result of certain activity or trauma, has a finite expected service life, and may need to be replaced at some time in the future. The patient should also be advised of other risks that the surgeon believes should be disclosed. The patient should be advised that any noise or unusual sensation should be reported to the surgeon as it may indicate implant malfunction.
4. Specialized instruments are available and must be used to assure the accurate implantation of prosthetic components. Careful attention must be given to accurately installing the prosthesis. Do not mix instruments from different manufacturers. While rare, breakage of instruments may occur especially with extensive use or excessive force. For this reason, instruments should be examined for wear or damage prior to surgery.
5. Preoperative templates should be used to assure proper sizing of prostheses. Use only with mating Stryker prosthetic components of appropriate size. Mismatching of components could impede component articulation, leading to wear and possible failure of the component and also contribute to joint laxity.
6. Periodic post-operative x-rays are recommended for close comparison with early post-op conditions to detect long term evidence of changes in position, loosening, bending, or cracking of components.
7. As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, immunosuppressive therapy, or high dosage radiation therapy.

Potential complications
Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component. The surgeon must be thoroughly familiar with the implant, instruments, and surgical procedure prior to performing surgery. Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.

Proper surgical procedures and techniques are the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure based on personal medical training and experience. Although Stryker technology, inc. (Stryker) cannot recommend a particular surgical technique suitable for all patients, a detailed surgical technique is available for surgeon reference. Medical procedures for optimal utilization of the prosthesis should be determined by the physician. However, the physician is advised that there is recent evidence that the potential for deep sepsis following total joint arthroplasty may be reduced by:
1. Consistent use of prophylactic antibiotics.
2. Utilizing a laminar flow clean air system.
3. Having all operating room personnel, including observers, properly attired.
4. Protecting instruments from airborne contamination.
5. Impermeable draping.

Caution
This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at **www.stryker.com** for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

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