



INSTRUCTION FOR USE DENTAL IMPLANT

Manufacturer – Genxt Medtech Pvt Ltd

Registrar Office- Pl.No.11, Nanda Dental Care Bldg.,Lane M, Opp. Army Sports Complex, Mundhwa Road,, Pune, Pune, Maharashtra, India, 411001 Email : medtech@genxtimplants.com.

Manufacturing Site - Genxt Medtech Pvt Ltd Plot No 43, S. No.119, Lane No. 8-B, Ramtekdi Industrial Estate Hadapsar Pune 411013 .

Website – www.genxtimplants.com

Description - Genxt Dental Implant System is a system of endosseous dental implants made from biocompatible Titanium Alloy (Ti6Al4V) with corresponding abutments, healing abutments, covering and fixing screws, other prosthetic parts and surgical instruments.

Intended Use - Dental Implant to be placed in bone to support a prosthesis - Teeth/gums/maxillofacial

Indication For Use –

-Suitable for replacing individual missing teeth, restoring both function and aesthetics.

- Implant system excels in replacing multiple missing teeth, offering comprehensive dental restoration solutions.
- The cause of tooth loss varies and is not restricted unless explicitly contraindicated. Implant selection, irrespective of surgical protocols or tooth location, is the implantologist's prerogative, with manufacturers only specifying contraindications, not indications.

Contraindications :

1. Uncontrolled Systemic Diseases: Patients with unmanaged systemic conditions, such as uncontrolled diabetes, may not be suitable candidates due to impaired healing.
2. Inadequate Bone Quantity or Quality: Insufficient bone volume or density in the implant site can hinder successful osseointegration and stability.
3. Active Infection at Implant Site: Presence of an ongoing infection in the oral cavity or at the proposed implant site may compromise the healing process and implant success.
4. Allergies to Implant Materials: Individuals with known allergies to the materials used in the implant should avoid implantation to prevent adverse reactions.

Warnings and Precautions

1. Only trained and experienced dental professionals should perform implant surgeries.
2. Use sterile instruments and aseptic techniques during implantation.
3. Avoid excessive force or torque during implant placement.
4. Monitor patients for any signs of infection, pain, or discomfort during the healing period.

Implantation Procedure

1. Preoperative Evaluation

Conduct a thorough patient assessment, including a review of medical and dental history.

Assess bone quality and quantity using appropriate diagnostic imaging techniques.

Develop a treatment plan based on the patient's specific needs, including implant type and placement location.

2. Surgical Technique

1. Administer local anesthesia to ensure patient comfort.
2. Make an aseptic incision at the designated implant site, following sterile procedures.
3. Prepare the osteotomy site with careful attention to depth and diameter according to the chosen implant size.
4. Place the Genxt Dental Implant System into the prepared site with precision.
5. Ensure proper implant alignment and orientation.
6. Achieve adequate primary stability through controlled torque during placement.
7. Close the surgical site with appropriate sutures, ensuring proper tissue adaptation.
8. Provide the patient with postoperative care instructions, including oral hygiene and dietary restrictions.

3. Postoperative Care

1. Advise the patient to maintain excellent oral hygiene to prevent infection.

2. Schedule regular follow-up appointments to monitor healing and implant stability.
3. Manage any postoperative complications promptly and appropriately.

Complications and Adverse Reactions

- Monitor the patient for potential complications such as infection, implant failure, or peri-implantitis.
- Be vigilant for any adverse reactions, including allergic responses to implant materials.

Maintenance and Follow-up

- Schedule periodic follow-up visits to assess implant integration and overall oral health.
- Provide the patient with long-term implant care instructions to ensure longevity and optimal function.

Sterilization and Storage

- Follow proper sterilization protocols for all implant components.
- Store implants and associated materials in a controlled, sterile environment.

Disposal

Dispose of any unused or expired implants and associated materials in accordance with local regulations.

Symbols-

Sr No	Symbol	Symbol Detail
1		Manufacturer
2		Date of Manufacturer
3		Use by Date
4		Batch Code
5		Sterilize Use Irradiation
6		No Resterilize
7		No Reuse

8		Do not use if package is damaged and consult instructions for use
9		Sunlight Away
10		Keep Dry
11		Medical Device
12		Non Pyrogenic
13		Caution
14		Consult Instruction For Use