Instructions for Use

Tactoset® Injectable Bone Substitute

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Products may not be available in all markets. Product availability is subject to the regulatory clearance in individual markets. Please contact your local representative if you have questions about product availability in your area.

℞ ONLY

Caution: Federal Law restrict this device to sale by or on the order of a physician.

AML 3000167 REV-A 2024-01

Read these instructions completely prior to use.

DEVICE DESCRIPTION
Tactoset® Injectable Bone Substitute is a synthetic, biocompatible bone graft substitute material that hardens and converts to a poorly crystalline hydroxyapatite at body temperature. The liquid component contains 194 mg/mL iohexol (i.e., 90 mg/mL iodine concentration) radiopacifier to enhance visualization of the implant. It is provided in single patient, single use kits.

INTENDED USE / INDICATIONS
Tactoset Injectable Bone Substitute is a synthetic, biocompatible bone graft substitute material that hardens and converts to a poorly crystalline hydroxyapatite at body temperature. It is indicated for filling bone voids or defects of the skeletal system (i.e. extremities and pelvis) that are not intrinsic to the stability of bony structure. These defects may be surgically-created osseous defects or defects created from traumatic injury to the bone. The device provides an injectable, self-setting, osteoconductive bone graft substitute that resorbs and is replaced by the growth of new bone during the healing process. Tactoset Injectable Bone Substitute can augment hardware and support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

DURATION OF ADMINISTRATION
Tactoset Injectable Bone Substitute is intended for permanent implantation.

CONTRAINDICATIONS
Do not use this product if one or more of the following conditions are present:
- Existing acute or chronic infections, especially at the site of the operation.
- Nonviable bone.
- Areas where surrounding bone is not viable or not capable of supporting and anchoring the implant.
- Altered calcium metabolism.
- Metabolic bone disease.
- Immunologic abnormalities.
- Systemic disorders which result in poor wound healing.
- Inflammatory bone disease.
- Acute traumatic injuries with open wounds close to the defect which are likely to become infected.
- Conditions where the surgical site may be subjected to excessive impact or stresses, including those beyond the load strength of fixation hardware.
- Hypersensitivity to iohexol or any of the excipients.
- History of serious reaction to iohexol or iodine-based radiocontrast agents.
- Known hyperthyroidism or autonomous thyroid adenoma.
- Manifest thyrotoxicosis.
- Pregnancy.
- Breastfeeding.
- Load bearing applications.

METHOD OF STERILIZATION
- Powder is provided STERILE via gamma irradiation (Cobalt ^{60}Co).
- Liquid is provided STERILE via steam sterilization.
- Liquid syringe and packaging is provided STERILE via vaporized hydrogen peroxide.
- Contents are STERILE unless the barrier packaging is open or damaged; DO NOT USE if the package is open or damaged.
- Contents are non-pyrogenic.

PRODUCT STORAGE
Store at controlled room temperature within 15 to 25°C (59 to 77°F).
- The expiration date is printed on the outer package label and patient record labels.
- DO NOT USE expired product.

WARNINGS
- DISCARD UNUSED PORTIONS; Tactoset Injectable Bone Substitute is a SINGLE PATIENT, SINGLE USE product.
- DO NOT RESTERILIZE; the safety and effectiveness of reused or resterilized Tactoset Injectable Bone Substitute is unknown.
- Because Tactoset Injectable Bone Substitute is indicated for use in defects that are not intrinsic to the stability of the bony structure, it is critical that adequate fixation be provided for unstable defects by other means.

- The safety and effectiveness for patients having received or to receive chemotherapy or radiation therapy at or near the implant site is not known.
- The safety and effectiveness when used in conjunction with other legally marketed devices having similar indications is not known.
- The safety and effectiveness for use in children or elderly patients is not known.
- The effect in patients with documented renal disease is not known.
- The effect in patients with metabolic bone disease is not known.
- The effect in patients that are pregnant/nursing is not known.
- The effect in patients with cardiovascular disease precluding elective surgery is not known.
- The effect in patients having had infection during the last 3 months is not known.
- Care must be taken to prevent the creation of emboli. Highly pressurized application of Tactoset Injectable Bone Substitute into a tightly confined space with ready venous or arterial access is not recommended, as the potential for formation of emboli is unknown.
- Prepare Tactoset Injectable Bone Substitute using only the specified Mixing Solution and volume; the effect of preparing with other substances or volumes is unknown and may adversely affect product performance.
- The performance of Tactoset containing iohexol radiopacifier was compared to the predicate device, Tactoset (without iohexol), in a rabbit critical sized femoral defect model. At the 26-week timepoint, animal study data demonstrated an average new bone formation of approximately 17% in the Tactoset with iohexol group, and 17% in the Tactoset (predicate) group. Animal study data at 26 weeks demonstrated that approximately 61% of implant material remained in the Tactoset with iohexol group, and 59% remained in the Tactoset (predicate) group, with respect to the geometry of the defect filled with implant material at the time of surgery. At 12 weeks the empty defect contained approximately 6% bone. Clinical performance has not been evaluated. Patients should be monitored to ensure adequate bone healing and minimize the risk of hardware failure.
- Do not use in infected sites.

PRECAUTIONS

- Only for use by surgeons familiar with the material, appropriate surgical techniques, and bone repair procedures.
- Use aseptic technique to minimize the risk of infection.
- Mix with the specified Mixing Solution; deviations will alter the consistency of the material and may adversely affect the setting reaction and the effectiveness of the implant.
- Do not disturb the material after implantation as disruption may affect the characteristics of the hardened material.
- Do not irrigate the defect site immediately after implantation; wait until the material is hard to touch (about 10 minutes at 37 °C, 98 °F).
- Fully fill the defect site to obtain maximum contact between Tactoset Injectable Bone Substitute and host bone. Not doing so may lead to incomplete or lack of bone formation, delayed union or non-union.
- Do not overfill the defect; Over-pressurizing the device may lead to extrusion beyond the site of intended application and damage to surrounding tissue. Remove any excess material within 2 minutes following implantation.
- The insertion of fixation implants after hardening may fracture the Tactoset Injectable Bone Substitute material.
- Follow general surgical protocol regarding use of fixation.
- Post-operative use of a closed suction drain is recommended.
- Do not administer to patients with known hypersensitivity (allergy) to hyaluronate preparations.
- Special caution is required for patients with a history of asthma, allergy or reactions to iodine-based radio contrast agents.
- Anaphylactoid reactions or other serious hypersensitivity reactions may be provoked by iodine-based contrast media, therefore, an immediate course of action, such as drugs available for treatment, should be planned prior to use.
- Ensure adequate hydration prior to and following administration of contrast media; special precaution of hydration should be taken with patients with renal dysfunction, multiple myeloma, diabetes mellitus, and elderly patients.
- Patients that are predisposed for seizures or have an increased risk for seizures, including a patient with a history of epilepsy, acute cerebral pathology, tumors, alcoholism, or drug addiction, require particular care.
- Patients with severe cardiovascular disease and pulmonary hypertension may develop hemodynamic changes or arrythmias and require particular care.
- Particular care should be taken with patients at risk of acute renal failure following administration of contrast media, including patients with renal impairment, diabetes mellitus, or paraproteinemias (myelomatosis and Waldenström´s macroglobulinemia).

POSSIBLE COMPLICATIONS

Re-operation to remove or replace the implant may be required occasionally due to medical reasons or device failure; if corrective action is not taken, one or more of the following complications may occur:

- Tissue thinning over implant site.
- Tenderness/redness/edema.
- Seroma/hematoma or infection.
- Swelling/fluid collection.

- Loss of contour.
- Migration, extrusion, dehiscence, fracture and sloughing of Tactoset Injectable Bone Substitute can occur as a result of excessive trauma or post-operative load bearing.
- Neurovascular injuries due to surgical trauma.

INTERACTION (IOHEXOL RELATED)

- Development of lactic acidosis is a risk for diabetic patients who are treated with metformin following administration of iodinated radio contrast agents.
- Transient hepatic dysfunction is a potential risk. For patients with both renal and hepatic function disturbances, clearance of iodinated contrast agent may be significantly delayed, and special care is required.
- Myasthenia gravis symptoms may be aggravated by iodinated contrast agents.
- To avoid hypertensive crisis, alpha blockers should be prophylactically given to patients undergoing procedures for phaeochromocytoma.
- Particular care should be given to patients with hyperthyroidism.
- An increased risk of delayed adverse reactions such as skin reactions for flu-like symptoms have been associated with iodinated contrast agents administered to patients treated with interleukin-2 within less than two weeks. Administration of iodinated contrast media to patients with multinodular goiter may be at risk for developing hyperthyroidism**.**

MIXING INSTRUCTIONS

The kit components are identified as follows:

1. Mixing syringe containing Tactoset Injectable Bone Substitute powder
2. Glass syringe containing Tactoset Injectable Bone Substitute setting solution
3. Female-female Luer lock connectors
4. 1 mL Luer lock syringes

STEP 1: HYDRATE TACTOSET INJECTABLE BONE SUBSTITUTE POWDER

Hydration is achieved as follows:

- Transfer kit components into the sterile field using sterile technique.
- Discard packaging.
- Remove the cap from the glass syringe containing the setting solution.
- Remove the cap from the mixing syringe containing the powder (do not discard).
- The powder is hydrated with the entire 4 mL supplied setting solution.
- Using a female-female Luer lock connector, attach the glass syringe containing the setting solution to the mixing syringe containing the powder.
- Hold the syringes vertically with the glass syringe containing the setting solution on top and inject the setting solution into the mixing syringe containing the powder.
- Remove the glass syringe and Luer lock connector and recap the mixing syringe.
- Remove the plunger rod sleeve (do not discard). Using the rod of the integrated mixing device, continuously mix the material from top to bottom of the mixing syringe for one minute.
- Reattach the plunger rod sleeve. Attach a Luer lock connector to the mixing syringe and expel residual air until a small drop of Tactoset Injectable Bone Substitute is ejected.
- Attach a 1 mL Luer lock syringe. Fill the 1 mL syringe to 0.9 mL. Fill and repeat as needed with remaining syringes.

⚠ **Hydrate powder with only the specified mixing solution and volume; deviations will alter the consistency of the material and may adversely affect the setting reaction and effectiveness of the implant.**

STEP2: INJECT

⚠ **Working time is 7-18 minutes from when the powder and setting solution make contact; material must be implanted in this time.**

⚠ **Setting time is an inverse function of local body temperature; approximately 10 minutes at 37 °C (98 °F).**

- Tactoset Injectable Bone Substitute is intended to be injected. It should not be implanted as a putty.
- To inject, use an 11-15 Ga Delivery Cannula.
- Fully fill the defect site to obtain maximum contact between Tactoset Injectable Bone Substitute and host bone; however, do not over-fill or over-pressurize the defect site.
- Remove excess material prior to hardening and avoid disturbing to allow proper setting.
- Allow approximately 10 minutes after injection for Tactoset Injectable Bone Substitute to harden prior to irrigating.
- Close the defect and follow general surgical protocol regarding post-operative use of closed suction drain.

Rx ONLY	CAUTION: Federal Law restrict this device to sale by or on the order of a physician	www.anikaifu.com	Consult electronic instructions for use
STERILE R	Sterilized using irradiation	LOT	Lot number
STERILE	Sterilized using steam or dry heat		Use by date
STERILE H_2O_2	Sterilized using vapor		Manufacturer
	Do not reuse		Date of manufacture
	Do not use if package is damage and consult instructions for use	REF	Catalog number
25°C 15°C	Temperature limit		Keep dry
	Keep away from sunlight	UDI	Unique device identifier
STERILIZE	Do not resterilize		

FOR FURTHER INFORMATION
If further information on this product is needed, please contact Anika Customer Service at 1-888-721-1600 in the U.S., or an authorized representative.

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