Tactoset®

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

INSTRUCTIONS FOR USE

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. 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 and may be combined with autogenous bone marrow.

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.

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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 Solutions and volumes; the effect of preparing with other substances or volumes is unknown and may adversely affect product performance.
- An animal performance study comparing both Tactoset and Tactoset with Bone Marrow Aspirate (BMA) to an empty defect negative control group demonstrated low rates of new bone formation at 12 weeks. Animal study data demonstrated that more than 50% of the implant material remained at 12 weeks following implantation. 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 volume of Mixing Solutions; 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.

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.

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 or can be hydrated with 3 mL of the supplied setting solution combined with 1 mL of autogenous bone marrow, aspirated using standard techniques.
- If combining with autogenous bone marrow aspirate, expel and discard 1 mL of setting solution using a female-female Luer lock connector and a sterile 1 mL syringe, and replace with 1 mL of bone marrow aspirate for a final 4 mL mixing solution volume.
- 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 solutions and volumes; deviations will alter the consistency of the material and may adversely affect the setting reaction and effectiveness of the implant.

STEP 2: 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.

	Consult Instructions for use	LOT	Batch, LOT	℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution		Use by		Do not use if package is damaged or opened
	Do not re-use		Manufacturer		Keep away from sunlight
STERILE R	Sterilized using radiation	REF	Catalog Number		
STERILE	Sterilized using steam		Keep Dry	15°C 25°C	Temperature Limit
STERILE H_2O_2	Sterilized using vaporized hydrogen peroxide				

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