

Injectable HA Bone Substitute Product Overview

HydroSet™ is a self-setting calcium phosphate bone substitute.

HydroSet™ is indicated to fill bony voids or gaps of the skeletal system (i.e., extremities, craniofacial, spine, and pelvis). These defects may be surgically created or osseous defects created from traumatic injury to the bone. HydroSet™ is indicated only for bony voids or gaps that are not intrinsic to the stability of the bony structure.

HydroSet™ cured *in situ* provides an open void/gap filler that can augment provisional hardware (e.g., K-Wires, plates, screws) to help support bone fragments during the surgical procedure. The cured cement acts only as a temporary support media and is not intended to provide structural support during the healing process.

Handling Characteristics

HydroSet™ is a quick-setting bone substitute that is easy to mix and deliver via hand application or syringe injection. The following times are from when the liquid is added to the powder.

Mixing Time: 0-45 seconds

Transfer Time: 45 seconds – 2 minutes and 30 seconds

Injection Time: 2 minutes and 30 seconds to 4 minutes and 30 seconds

Setting Time: 4 minutes and 30 seconds to 8 minutes and 30 seconds (32°C)

*HydroSet™ is temperature sensitive, therefore, handling times are approximate based on average product and OR temperatures of 18 to 22°C (approx. 64-72°F).

Chemical Composition

Powder: 1. Dicalcium phosphate dihydrate 2. Tetracalcium phosphate 3. Tri-sodium citrate

Liquid: 1. Sodium phosphate 2. Polyvinylpyrrolidone 3. Water

Packaging and Sterility

HydroSet™ is packaged sterile in exact, pre-measured ingredients. The product should be used within 60 minutes of opening the outer powder packaging.

There are two separate sterile packs. (Syringe and cannula are for one-time use only. Do not resterilize).

1. Foil Pouch: The powder is packaged in a plastic bowl. The bowl is placed in a Tyvek® container. Underneath the bowl containing the powder is a desiccant to control moisture. This should never be implanted or mixed with the powder. The Tyvek® container is placed in a foil pouch and it is sterilized via gamma irradiation.

2. Liquid Blister Kit: The packaging which contains the sterile filled liquid syringe also includes the cement delivery syringe, cannula and mixing spatula which are sterilized via Ethylene oxide.

Sizes offered: 3cc, 5cc, 10cc, 15cc

Storage Information

Room temperature between 15 and 25°C (approx. 59-77°F).



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