

HARVEST GRAFT DELIVERY SYSTEM

INSTRUCTIONS FOR USE

Indications for Use: The Harvest Graft Delivery System is indicated for the delivery of allograft, autograft, or synthetic bone graft materials to an orthopedic surgical site. In addition, it is designed to facilitate pre-mixing of bone graft materials with I.V. fluids, blood, plasma, platelet rich plasma, bone marrow, or other specific blood component(s) as deemed necessary by the clinical use requirements.

Warnings: 1) Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.

Precautions: 1) Inspect product prior to use, do not use if package is damaged or opened; 2) Read instructions prior to use; 3) Aseptic technique required; 4) Dispose of blood contaminated materials following hospital policy and procedures for biological waste, use Universal Precautions; 4) For single use only do not resterilize.

Graft Hydration Kit (GDP-10):

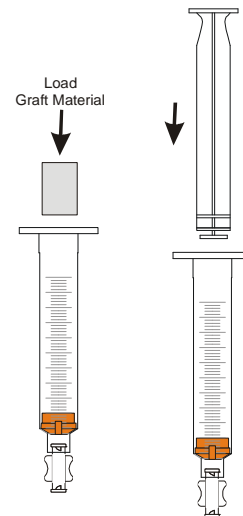
- 1- Syringe/Piston/Fem-Fem Luer Assembly
- 1 -Mixing Nozzle
- 1- Petri Dish
- 1- Pusher Assembly
- 1- 1 ml Syringe
- 1- 10 ml Syringe
- 1- Clip, 10:1
- 1- Gauze Pad

Graft Hydration Kit (GDP-10i):

- 1- Syringe/Piston/Fem-Fem Luer Assembly
- 1 -Mixing Nozzle
- 1- Petri Dish
- 1- Pusher Assembly
- 1- 3 ml Syringe
- 1- 10 ml Syringe
- 1- Clip, 10:3
- 1- Gauze Pad

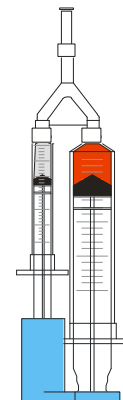
STEP 1: Loading Graft Material(s)

1. Remove plunger from Graft Syringe/Infusion Chamber and fill with the desired amount of graft material(s).
2. Replace plunger. If necessary the plunger can be used to compress the graft material.



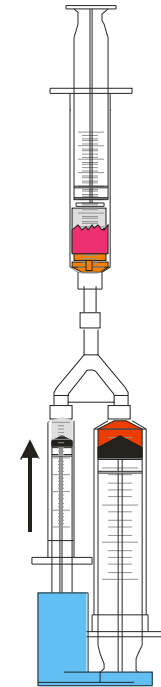
STEP 2: Preparing Liquid Applicator

1. Fill liquid applicator syringes with fluid of surgeon's choice.
Note: Anticoagulant (e.g., heparin) is required when collecting bone marrow aspirate.
2. Attach one fluid filled syringe to each luer of the applicator tip.
3. Attach two-sided luer onto applicator tip.
4. Install plunger clip to syringe plungers.



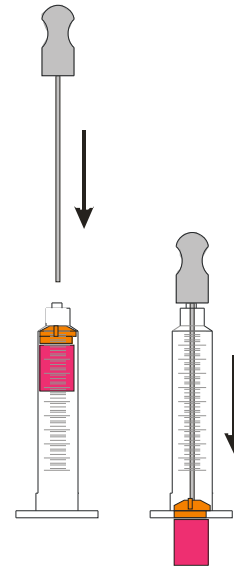
STEP 3: Inject Fluids Into Graft Syringe/Infusion Chamber

1. Attach Liquid Applicator to luer end of Graft Syringe/Infusion Chamber.
2. Slowly inject contents of Applicator.
3. Remove Applicator, mix and allow materials to clot.



STEP 4: Remove Bone Graft Material From Graft Syringe/Infusion Chamber.

1. Withdraw plunger from syringe.
2. Install push rod through syringe luer.
3. Move push rod forward to expel contents from Graft Syringe/Infusion Chamber.



CAUTION: Excess blood products should be disposed of in accordance with policies for disposal of biohazardous waste.

HARVEST[®]

Developing technologies for accelerating healing, *naturally*[™]

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