

BIOLOGICS



**Recombinant Human Bone Morphogenetic Protein-2 (rhBMP-2)
Placed on an Absorbable Collagen Sponge (ACS)**

INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device

Sizes

Small Kit – 2.8ml (cc), One Package of 2 One Inch x Two Inch ACS, Part #7510200; For LT-CAGE Sizes: 14x20mm, 14x23mm, 16x20mm

Medium Kit – 5.6ml (cc), One Package of 4 One Inch x Two Inch ACS, Part #7510400; For LT-CAGE Sizes: 16x23mm, 16x26mm, 18x23mm

Large Kit – 8.0ml (cc), One Package of 6 One Inch x Two Inch ACS, Part #7510600; For LT-CAGE Sizes: 18x26mm

Large II Kit – 8.0ml (cc), One Package of 1 Three Inch x Four Inch ACS, Part #7510800; For LT-CAGE Sizes: 18x26mm



**15% Hydroxyapatite/
85% Beta-Tricalcium Phosphate Ceramic**

MASTERGRAFT® Resorbable Ceramic Granules

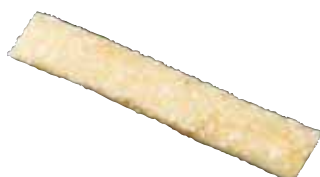
Sizes

5cc Vial (Yellow) - Part #7600105

15cc Vial (Orange) - Part #7600115

10cc Vial (Green) - Part #7600110

30cc Vial (Blue) - Part #7600130



Allograft Tissue – Frozen and Freeze Dried (RT-Room Temperature)

OSTEOFIL® Allografts

Sizes

Frozen

OSTEOFIL Allograft Bone Paste, Syringe – 1cc, 5cc, 10cc

OSTEOFIL ICM Moldable Strips – 20x50mm, 20x90mm strips (Has Cortical/Cancellous Bone Chips)

OSTEOFIL ICM Moldable Paste, Syringe – 5cc, 10cc, 20cc (Has Cortical/Cancellous Bone Chips)

Freeze dried (RT-room temperature)

OSTEOFIL RT Paste - .5cc, 1cc, 5cc, 10cc syringes

OSTEOFIL RT ICM Moldable Paste – 5cc, 10cc (Has Cortical/Cancellous Bone Chips)

BRIEF SUMMARY OF INDICATIONS, CONTRAINDICATIONS, AND WARNINGS FOR: INFUSE® BONE GRAFT/LT-CAGE® LUMBAR TAPERED FUSION DEVICE INFUSE® BONE GRAFT/INTER FIX™ THREADED FUSION DEVICE INFUSE® BONE GRAFT/INTER FIX™ RP THREADED FUSION DEVICE

The INFUSE® Bone Graft/Interbody Fusion Device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade 1 spondylolisthesis or Grade 1 retrolisthesis at the involved level. The INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device (Flat Nose) is to be implanted via an anterior open or an anterior laparoscopic approach. The INFUSE® Bone Graft/LT-CAGE® Lumbar Tapered Fusion Device (Round Nose) is to be implanted via an anterior open approach. INFUSE® Bone Graft with either the INTER FIX™ or INTER FIX™ RP Threaded Fusion Device is to be implanted via an anterior open approach.

The INFUSE® Bone Graft component must not be used without the Interbody Fusion Device component. These components must be used as a system.

NOTE: The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device may be use together to treat a spinal level. LT-CAGE® Lumbar Tapered Fusion Device implants are not to be used in conjunction with either the INTER FIX™ or INTER FIX™ RP implants to treat a spinal level.

The INFUSE® Bone Graft/Interbody Fusion Device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen or to other components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy or patients undergoing treatment for a malignancy, in patients who are skeletally immature, in pregnant women, or in patients with an active infection at the operative site or with an allergy to titanium or titanium alloy.

Antibody formation to rhBMP-2 or its influence on fetal development has not been assessed. The safety and effectiveness of this device has not been established in nursing mothers. Women of child-bearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate INFUSE® Bone Graft kit.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.