

(CSH/29/mai 2002)
(HSC/29/May 2002)

ANNEXE

CLASSEMENT D'UN SUBSTITUT DE GREFFON OSSEUX
SOUS FORME MEDICAMENTEUSE DENOMME "OSTEOSET^{M.D.}"

(Point VIII.4 de l'ordre du jour)

ANNEX

CLASSIFICATION OF A MEDICATED BONE GRAFT SUBSTITUTE
CALLED "OSTEOSET[®]"

(Item VIII.4 on Agenda)

OSTEOSET® INJECTOR

PRECISION PLACEMENT INSTRUMENTS



Preci-Graft® Instruments

Rigid, dissociable, stainless steel cannulae provide mechanical leverage for bone grafting with the OSTEOSET® INJECTOR.

INDICATIONS

- Percutaneous grafting procedures
- Tibial plateau fractures
- Benign bone cysts
- Colossal fractures
- Spine procedures
- Distal radius fractures
- ACL tunnel reconstruction
- Core decompression
- Backfill hardware removal
- Backfill biopsy sites



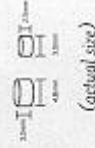
Radiopaque pellets being placed under fluoroscopy using the OSTEOSET® INJECTOR.

The disposable OSTEOSET® INJECTOR delivers precise, efficient placement of OSTEOSET® bone graft substitute pellets. Pre-loaded and pre-sterilized, the injector provides the ideal mechanism for the careful placement of each OSTEOSET® pellet to facilitate bone growth and a successful clinical outcome.

OSTEOSET® Bone Graft Substitute

SURGICAL GRADE
CALCIUM SULFATE

- Bioresorbable
- Biocompatible
- Cost-effective
- Disease/contaminant free
- Does not interfere with healing of infected site
- Extended shelf life
- Provides radiographic marker
- Convenient delivery options
- 3.0 and 4.8 mm pellets



WRIGHT MEDICAL TECHNOLOGY, INC.
B I O - O R T H O P A E D I C S G R O U P

5677 AIRLINE ROAD • ARLINGTON, TN, USA 38002
800-838-7188 • 901-867-9971 • WWW.WMT.COM

©1999 WRIGHT MEDICAL TECHNOLOGY, INC.

U.S. patent # 5,614,266. OSTEOSET® is a registered trademark of Wright Medical Technology, Inc.

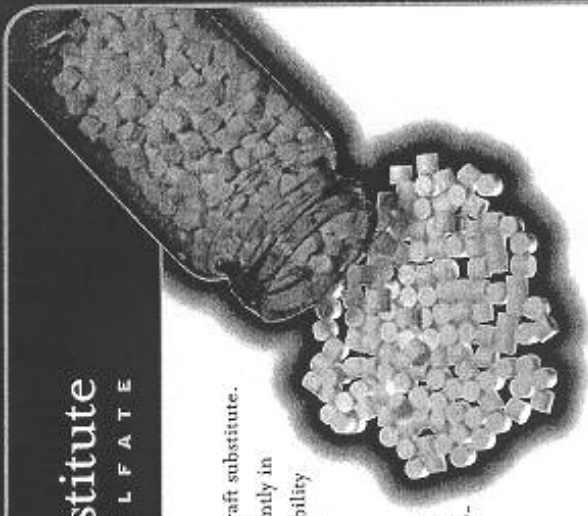
SKZ 929-059

OSTEOSET® Bone Graft Substitute

S U R G I C A L G R A D E C A L C I U M S U L F A T E

As early as 1892, medical literature describes the use of calcium sulfate as a bone graft substitute. In these early studies, calcium sulfate was found to completely resorb and aid significantly in bone repair. There were, however, subsequent studies demonstrating significant variability in clinical outcomes. These inconsistencies in performance prompted researchers to better understand and control the unrefined raw material.

Over the past 15 years, scientists and clinicians associated with United States Gypsum (USG) and Wright Medical Technology extensively studied and characterized calcium sulfate. It was discovered that by engineering the shape and size of the hemihydrate crystals, the resorption rate of the final product could be controlled, providing consistent clinical results. OSTEOSET® is the product of this research. The pellets offer a biological framework into which new bone can form, and are resorbed at a rate consistent with natural bone formation.



NON-SURGICAL GRADE CALCIUM SULFATE
Non-surgical grade material can result in inconsistent resorption rates which are not optimal for bone repair.



PROPRIETARY PROCESSING
Specially-designed equipment produces the pure surgical grade alpha hemihydrate used for OSTEOSET.

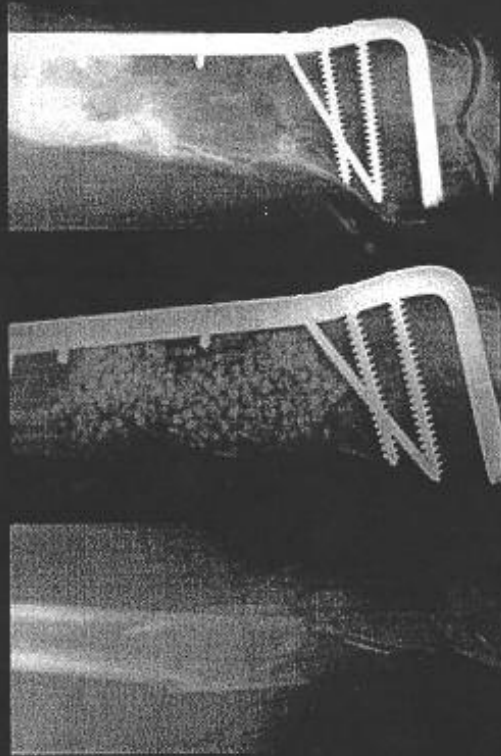


SURGICAL GRADE CALCIUM SULFATE
Uniform crystalline structure provides controlled rate of resorption.

C A S E # 3 4 4

Proven Clinically for Trauma

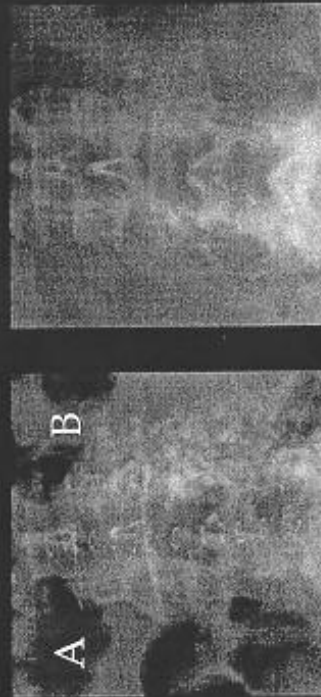
- Fifty-eight year old female sustained supracondylar fracture.
- OSTEASET® utilized as primary graft material
- One year radiograph demonstrates dramatic healing response



C A S E # 5 8 2

Proven Clinically for Spine

- Iliac bone crest utilized alone (A), OSTEASET® utilized as a bone graft extender with local autograft (B).
- 3 month film demonstrates impressive bone response with OSTEASET® mixed with local bone (B), as compared to iliac crest bone (A) alone.



C A S E # 2 4 8

Proven Clinically for Benign Cysts

- 5 year-old girl developed a pathological fracture through an aneurysmal cyst of the forearm
- Cyst carefully debrided and packed with OSTEASET® pellets
- At 5 months the bone has remodeled and the cyst is no longer discernible



5 MONTH POST-OP

1 DAY POST-OP

PRE-OP

C A S E # 3 9

Proven Clinically for Adult Reconstruction

- 72 year old male required revision knee surgery
- Significant defect posterior to tibial stem was packed with OSTEASET® pellets
- 9 month film demonstrates dramatic bone response in the proximal tibia.



9 MONTH POST-OP

6 WEEK POST-OP

POST-OP DAY 1