

Bioabsorbable bone plug  
**BIOSEM II**



**SEM** science  
et  
médecine



## Presentation



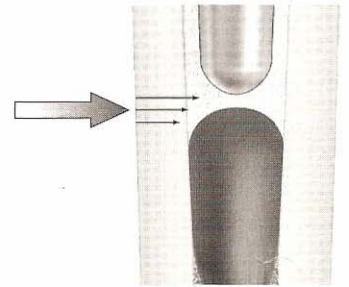
The BIOSEM II is a flexible bioabsorbable bone plug :

- allows pressurization of cement, while avoiding spreading of cement in the distal shaft,
- enhances cement fixation,
- minimizes elevation of temperature due to cement polymerization,
- in case of revision, stem extraction is easier because there is no permanent distal plug below the cement mantle.

Its unique rounded shape prevents stress concentration at the distal end of the cemented stem, thus avoiding weakening of the femur.

The BIOSEM II is flexible and available in a large choice of sizes to meet all morphological requirements, while eliminating the risk of hyperpressure within the femoral shaft.

The BIOSEM II bioabsorbable bone plug does not cause postoperative pyrogenic reactions.



## Materials

The BIOSEM II bone plug is manufactured from bovine pharmaceutical gelatin. Full traceability is provided. Characteristics of animals and raw materials used in the manufacturing process of gelatin are known (NF V 46-007). It can therefore be guaranteed that they have never been in contact with animals with transmissible diseases.

The BIOSEM II bone plug has been approved by the microbiological safety expert committee, Ministry of Employment and Social Affairs.

Approval : 96-039 01B02, November 21, 1996.

Composition :

- Pharmaceutical gelatin : 45 %
- Distilled water : 30 %
- Glycerol : 25 %.

The BIOSEM II bone plug is sterilized using  $\beta$  radiation.

## Storage

The BIOSEM II bone plug should be stored in a cool place, preferably in a refrigerator, at less than 20°C of temperature.

## Contraindications

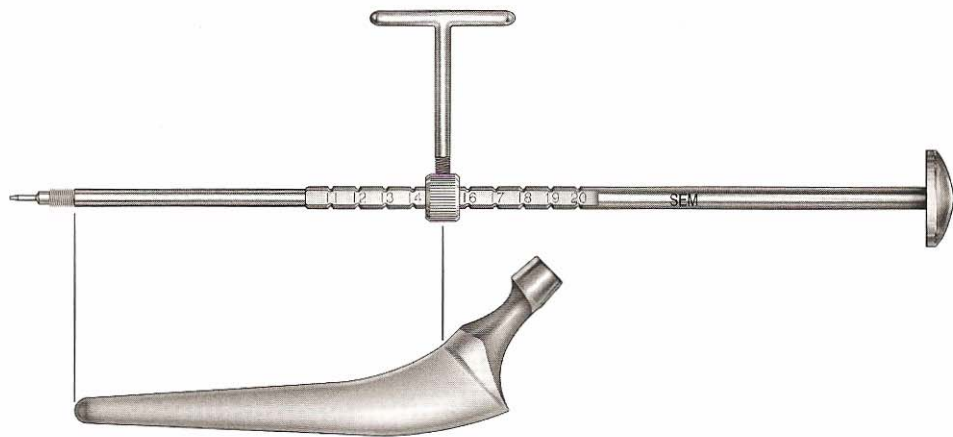
The following adverse effects have been associated with the use of intramedullary plugs and may occur with the BIOSEM II bone plug :

- allergies and other reactions to device materials,
- cardiovascular disorders (including thrombus ...) and complications associated with any orthopaedic device (infection ...).

The BIOSEM II bone plug is not indicated with cementless arthroplasty.

## Surgical technique

Following preparation of the femoral canal with appropriate broaches or reamers, adjust insertion depth, according to the length of the trial stem or the corresponding broach.



Trial plugs are available for bone plug sizing. The trial plug is fully threaded onto the calibrated plug impactor. Proper fit is determined by the trial which fits snugly in the canal as the BIOSEM II bone plug should not be allowed to migrate distally under the pressure of cement.



Remove the trial and assemble the cement plug spacer one size smaller than the trial, or of the same size.

The appropriately sized bone plug is fixed to the blunt tip of the pusher and then impacted.



A certain amount of resistance should be met during impaction ; if not, the next larger bone plug can be inserted on top of the first one.

## Ordering information

### Implants

50.10.08	BIOSEM II-8	bone plug
50.10.09	BIOSEM II-9	bone plug
50.10.10	BIOSEM II-10	bone plug
50.10.11	BIOSEM II-11	bone plug
50.10.12	BIOSEM II-12	bone plug
50.10.13	BIOSEM II-13	bone plug
50.10.14	BIOSEM II-14	bone plug
50.10.15	BIOSEM II-15	bone plug
50.10.16	BIOSEM II-16	bone plug
50.10.18	BIOSEM II-18	bone plug



### Instruments

60.00.03	BIOSEM - Calibrated plug impactor, ø 8
60.00.50	BIOSEM - Ring
60.00.52	BIOSEM - Stop screw
64.00.08 à 18	BIOSEM - Trial plugs
64.00.28 à 38	BIOSEM - Cement plug spacer
69.18.15	Custom-formed container



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