

Cempadic®



Surgical technique
cement spacer hip

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Nota Bene: The author of this technique has outlined the procedure for the uncomplicated surgical scenario. Ultimately however it is the operating surgeon who is best placed to assess and address the individual needs of each patient.

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INTRODUCTION

Due to degenerative changes of the human joint, it may become necessary to replace the joint with a prosthesis. The joint replacement is a common and successful treatment. However, due to many reasons, a small number of patients that undergo such orthopaedic surgical procedure suffer from infection at the surgical site and generally around the implanted joint prosthesis. In order to cure such an infection in a two-stage re-implantation, the implanted joint prosthesis is generally removed, the site is thoroughly debrided and washed, antibiotics are applied to the infected site via temporary implant until the infection is eliminated and a new revision type joint prosthesis is then implanted during a subsequent orthopaedic surgical procedure. The temporary implants are usually pads made intraoperatively of bone cement with rough surfaces not suitable for articulating during continuous passive motion machines (CPM) used for mobilisation of the patients. Due to the lack of mobilisation, the joints are stiff and the soft tissues are very tight when the cement spacers are replaced by the final revision implant components.

Cempadic® cement spacer hip

Cempadic® Spacer (cement pads implantcast)



figure A Cempadic® EcoFit® stem 17,5



figure B acetabular mold 50mm

The Cempadic® spacer molds consisting of two parts and made of silicone allow the surgeon to customise a cement spacer with the EcoFit® hip stem design and a large head to achieve smooth articulating surfaces which allow the mobilisation of the patient with a low wear rate compared to hand made spacers.

The Cempadic® spacer molds are reusable and can be cleaned and resterilised as normal instruments. Optionally the hip spacer can be reinforced by the use of a $TiAl_6V_4$ rod.

Cempadic® hip molds are available in the femoral sizes 6,25 to 17,5 and the head diameters from 44 to 62mm. It is recommended to use the standard viscosity implabond bone cement with or without antibiotics.

Note: A set of Cempadic® hip spacer molds are manufactured upon request. ACS® total knee spacer molds are available, too.

The following explanation shows the cement mixing by spatula and bowl and the cement application by hand.

The mixing can be performed in a syringe or manually.

Generally, the use of a lavage system is recommended (see catalogue section).

According to the reprocessing instructions (RA_S00) the service life of the Cempadic® Spacer molds is limited to 25 reprocessing cycles. The molds are delivered non-sterile and have to be cleaned, disinfected and sterilized before each use.

Cempadic[®] cement spacer hip

Modelling of the spacers

The spacer consist of the stem and the large head part. It is made in a two-stage procedure. Determine the femoral and the head size. For the making of the spacers, different quantities of bone cement are necessary.

For the head a minimum of 60g and for the stem a minimum of 40g of bone cement is needed.

General instruction for use for implabond bone cement at a temperature of 20°C

Powder:

- Open the aluminum protective bag and take out its non-sterile content.
- Open the second non sterile bag and take out the sterile powder pouch.
- Carefully open the pouch and pour the whole of the powder into the bowl.

Liquid:

- Open the ampoule blister pack and take out the sterile ampoule.
- Do not break the ampoule above the bowl (risk of glass fragments falling into the powder).
- Pour the whole of the liquid onto the powder.

Manual application (implabond 1 and 1G)

- Mix carefully so as to minimise the entrapment of air bubbles for 45 seconds.
- Leave the mixture alone. Take the cement in gloved hands and knead it until it no longer adheres to the fingers (45 seconds to 2 minutes 15 seconds).
- After 2 minutes 15 seconds please insert the cement in the spacer mold.
- Hardening time in normal environmental conditions (temperature 20°C +/- 1°C, humidity 50% +/- 10%) is 9 minutes for implabond 1 and 10 minutes for implabond 1G.

Further information can be found in the instructions for use "implabond".

Cempadic[®] cement spacer hip

Modelling of the femoral spacer



figure 1a



figure 1b



figure 2



figure 3



figure 4

Mix the bone cement in a mixing bowl or with a syringe. If a syringe is used, remaining cement of the small amount of 40g may rest in the tube. Therefore we recommend to mix the cement in a bowl.

Please prevent that the non mixed liquid get in touch to the silicone mold, because this can cause lead to a change of the colour of the mold.

Put the powder and the liquid according to the suppliers instructions for use. With implabond bone cement you put first the powder and pour the liquid over it. Mix the cement for 45 seconds and leave the mixture alone for 2 minutes 15 seconds.

Open the stem mold of the determined size (fig. 1a) and form a role with a diameter of app. 2cm.

Take the cement in gloved hand and knead it until it no longer adheres to the fingers. No later then additional 3 minutes please fill this role into the open stem mold (fig. 1b).

Due to the determined size the amount of cement should be reduced according to the size (table 1).

Put the cover to the bottom part of the mold and compress. Make sure that the mold is completely filled and the stem geometry appears. Remove obsolete bone cement (fig. 2).

Keep the mold under pressure for about 3 minutes. After hardening of the cement (9 minutes (implabond 1) respectively 10 minutes (implabond 1G), at 20°C), open the mold and take out the molded femoral stem (fig. 3).

Check the surface of the stem. If necessary, please remove unevennesses. Shape the femoral stem by the use of a knife, chisel or forceps (fig. 4).

Please perform the shaping of the component far away from the patient not to risk sterility due to cement particles flying through the theatre.

Modelling of the big head by the use of the acetabular mold

Repeat the earlier described mixing procedure. Open the acetabular mold and fill a small portion of bone cement into the determined head size mold (fig. 5a and 5b).

Close the mold (fig. 5c).

Please slide the earlier made stem with the taper connection into the acetabular mold (fig. 6).

Stabilise the stem for app. 3 minutes in this position. After hardening of the cement (9 minutes (implabond 1) respectively 10 minutes (implabond 1G), at 20°C) open the mold and take out the molded hip spacer (fig. 7).

Check the mold and remove unevennesses. Shape the component by the use of a knife, chisel and forceps.

Please perform the shaping of the component far away from the patient, not to risk sterility due to cement particles flying through the theatre.

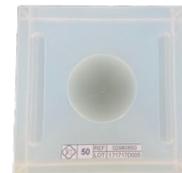


figure 5a

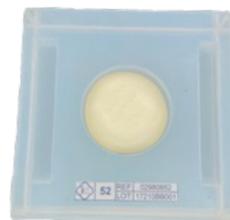


figure 5b



figure 5c



figure 6



figure 7

Cempadic[®] cement spacer hip

Check of the joint stability

Insert the cement spacer into the intramedullary femoral canal and perform a trial reduction in order to check the joint stability (fig. 8).

Inserting the spacer

The spacer should be inserted without cement.

Check the range of motion and the joint stability.

Please notice, that the customised spacers are gap filling pads which should enable the mobilisation by a continuous passive motion machine (CPM) for the time of infection therapy. Overloading can lead to increased cement wear or breakage of the components.



figure 8

Cempadic® cement spacer hip

MATERIAL

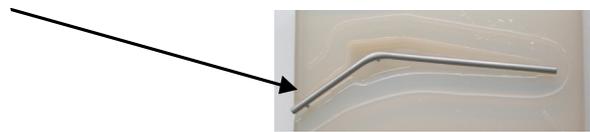
Cempadic® spacer mold EcoFit® stem

- 0298-0841 for EcoFit® stem 6,25
- 0298-0842 for EcoFit® stem 7,5
- 0298-0843 for EcoFit® stem 10
- 0298-0844 for EcoFit® stem 12,5
- 0298-0845 for EcoFit® stem 15
- 0298-0846 for EcoFit® stem 17,5



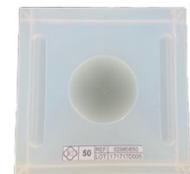
Cempadic® spacer rod EcoFit® stem (optional) (TiAl₆V₄) 4mm

- 0298-0861 for EcoFit® stem 6,25-10
- 0298-0862 for EcoFit® stem 12,5-17,5



Cempadic® acetabulum cement spacer mold

- 0298-0944 for 44mm
- 0298-0946 for 46mm
- 0298-0948 for 48mm
- 0298-0850 for 50mm
- 0298-0852 for 52mm
- 0298-0854 for 54mm
- 0298-0856 for 56mm
- 0298-0858 for 58mm
- 0298-0960 for 60mm
- 0298-0962 for 62mm



implabond bone cement 40g

- D041140 implabond 1
standard viscosity
- D041140G implabond 1G
standard viscosity with antibiotics



ic-Lavage

- 0067-8001 ic-Lavage set with nozzles and splash shield
- 0067-8002 ic-Lavage femoral brush with suction





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