Question and Answer:
CalForma™ Calcium Sulfate Bone Graft Barrier

Q: How is CalForma Calcium Sulfate Bone Graft Binder used?

A: Depending on defect size, CalForma may be used to cover bone grafting materials such as autogenous, allogenic, synthetic or xenogenic. After a bone graft has been placed into a defect, mix CalForma formulation with a pre-measured, hydrating solution, included in a pre-filled syringe. Mix the contents vigorously and thoroughly and mold the resulting putty over the bone graft to a thickness of 2mm. Suture the flaps, and within minutes, the calcium sulfate sets, forming a barrier to bone graft particle migration.

Q: What is CalForma made of?

A: CalForma is made of Calcium sulfate (alpha-hemihydrate) and HPMC (Hydroxypropylmethycellulose).

Q: What is HPMC?

A: Hydroxypropylmethylcellulose is an off-white powder that functions as a thickening agent and stabilizer. It is used in many pharmaceutical preparations and foods. It gives CalForma its unique handling characteristics.

Q: Can CalForma Calcium Sulfate Bone Graft Barrier be used as a bone graft material?

A: CalForma is not intended to be used by itself as a bone graft material.

Q: I've been using membranes for some time, and I'm not sure I want to make an effort to learn a new bone regeneration technique. Is it really worth my time and cost?

A: If you are concerned with time and cost, then you should definitely try CalForma. Because the material is resorbable, there is no second surgery for removal. There is no cutting, fitting and suturing because calcium sulfate is moldable and adhesive. Chairtime should be reduced because of CalForma's unique moldability and ease of placement with gloved fingers and CalForma's rapid set time.

Q: What about my patients? How will their experiences differ when I use calcium sulfate?

A: Because of the extraordinary biocompatibility and tissue-friendly nature of calcium sulfate, patients are unlikely to experience anything other than normal discomfort or inflammation attributable to the surgical procedure. In fact, users report significantly fewer post-operative problems compared to patients treated with many of the available membranes.

Q: Most of my problems with bone regeneration occur when I am unable to achieve complete tissue coverage or when my barrier becomes prematurely exposed. Can I expect calcium sulfate to be any different?

A: One of the most exciting features of calcium sulfate is that it allows soft tissue to heal over its surface, even when it is exposed, after flap closure. Exposed CalForma Barriers should be protected (i.e., periodontal dressing, denture base, acrylic stent or provisional bridge) for 14 days at which time soft tissues will have healed over the barrier.

Q: I've used calcium sulfate before, and I've found that blood or saliva at the surgical site prevents it from setting. How is the CalForma Calcium Sulfate Bone Graft Barrier different?

A: CalForma is unaffected by exposure to saliva or blood. However, excessive saliva and bleeding should be avoided.

Q: Is CalForma subject to cracking or breaking when suturing?

A: It is ideal to suture the flaps while the CalForma is still in a moldable form. Once the initial hard set (approximately 4 minutes) occurs, avoid putting direct pressure on the barrier. The flaps should be pre-sutured, and the knots tied as soon as the calcium sulfate barrier is in position. CalForma is very difficult to crack once it has fully hardened (approximately 30-60 minutes).

Q: I'm concerned that calcium sulfate may resorb too quickly. How do I know that the barrier is in place long enough for regeneration to occur?

A: CalForma is formulated to be an effective barrier for about 4 weeks and can be in the tissue for up to 6 weeks. This is more than sufficient time to allow for protection of the underlying bone graft so that its osteogenic potential can be realized.

Q: Has clinical research been conducted on the effectiveness of calcium sulfate as a barrier and as part of a composite graft?

A: CalForma is based on extensive initial and continuing clinical research (involving calcium sulfate). In addition, controlled clinical trials demonstrating the effectiveness of calcium sulfate have been conducted at the University of Louisville, University of Maryland, University of Nebraska, Case Western Reserve University, the University of Buffalo and Yonsei University in Seoul, Korea, and others. Abstracts and a bibliography of calcium sulfate articles are available upon request.

Q: How does CalForma Calcium Sulfate Bone Graft Barrier differ from other types of plaster?

A: Because there are no official guidelines, other manufacturers use the label "medical grade" on plaster formulations. CalForma is manufactured through a proprietary process and is **the purest form of calcium sulfate available**. In addition, **CalForma is a patented proprietary alpha-hemihydrate, which exhibits greater compressive strength and a more predictable resorption rate than other hemihydrate calcium sulfates**. This is due to the density, uniform particle shape, size and regular crystalline formation attributable to the surgical grade alpha-hemihydrate calcium sulfate in CalForma.

LIFECORE BIOMEDICAL

Manufacturer:
Lifecore Biomedical, Inc.
3515 Lyman Blvd.
Chaska, MN 55318 USA
Call: 800-752-2663
Fax: 800-651-8521

Outside the USA
Call: +1-952-368-4300
Fax: +1-952-368-4324

Authorized Representative:
Lifecore Biomedical, SpA
via A. Fleming, 19
37135 Verona, Italy
Call: +39-045-8230294
Fax: +39-045-8250296

Subsidiary:
Lifecore Biomedical, GmbH
Alfter, Germany
Call: +49-2222-9294-0
Fax: +49-2222-977356

Subsidiary:
Lifecore Biomedical, AB
Särö, Sweden
Call: +46-31-93-68-23
Fax:+46-31-93-68-45

Email: info@lifecore.com www.lifecore.com

10/04