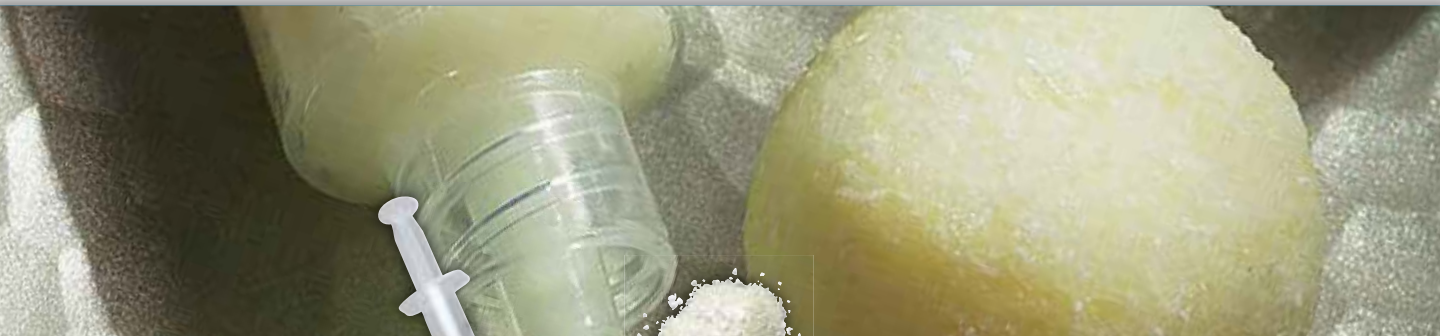


EXACTECH BIOLOGICS

Handling Instructions



Optecure[®]
Optecure[®]+ccc

ORTHOPAEDIC

Optecure[®]

Optecure	ABG	Blood or PBS (recommend max volumes)
1cc	1cc (1:1)	0.82ml
2cc	2cc (1:1)	1.6ml
5cc	5cc (1:1)	4.1ml
10cc	10cc (1:1)	8.2ml
20cc	20cc (1:1)	16.4ml

Optecure[®]+ccc

Optecure+ccc	ABG	Blood or PBS (recommend max volumes)
1cc	0.5cc (2:1)	0.68ml
2cc	1cc (2:1)	1.4ml
5cc	2.5cc (2:1)	3.4ml
10cc	5cc (2:1)	6.8ml
20cc	10cc (2:1)	13.6ml

*Optecure and Optecure+ccc can be used with autologous bone graft and bone marrow. Use of bone marrow with autologous bone graft is only for orthopaedic indications. For additional instructions, please consult the appropriate orthopaedic instructions for use.

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713-05-00 Rev. C
 Optecure Handling Instructions 0414

A Great Day in the O.R.™

HANDLING INSTRUCTIONS



1

What is required?

Everything required to prepare Optecure® is delivered in a single, room-temperature package:

- 1 jar of lyophilized dry mix Optecure (DBM, hydrogel carrier) or dry mix Optecure+ccc (DBM, ccc, hydrogel carrier)
- Sterilized buffered saline solution
- 1 sterilized mixing spatula



2

Open

Open the box of Optecure and remove the two pouches.

POUCH 1:

- The sterile inner pouch contains buffered saline solution and a mixing spatula.
- Open the outer pouch and introduce the inner pouch into the sterile field.

POUCH 2:

- **Optecure:** The sterile inner foil pouch contains aseptically processed Optecure DBM and a carrier in a plastic jar.
- **Optecure+ccc:** The sterile inner foil pouch contains aseptically processed Optecure DBM, irradiated ccc and a carrier in a plastic jar.
- Open the outer pouch and introduce the inner foil pouch into the sterile field.



3



4

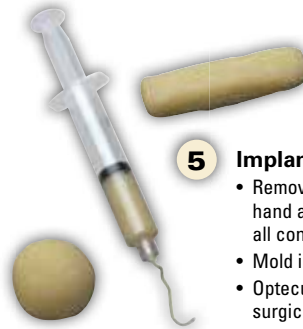
Autogenous Bone Graft (ABG)

- **Optecure:** Combine Optecure 1:1 with autogenous bone for use as a bone graft extender.
- **Optecure+ccc:** Combine Optecure+ccc 2:1 with autogenous bone for use as a bone graft extender. (Two parts Optecure+ccc to one part autogenous bone.)
- Add the measured bone into the jar of Optecure or into the jar of Optecure+ccc.
- Mix the contents until putty is formed. If needed, use additional blood or buffered saline to achieve the consistency desired for each surgical situation.
- Additional bone marrow may be added to the mixture of hydrated Optecure/Optecure+CCC and ABG.
Note: Use of bone marrow is only for orthopaedic indications.

Optecure hydration

Note: Optecure and Optecure+ccc may be prepared with different diluents (see tables on reverse). Using maximum volumes of diluents recommended will deliver a more flowable putty. If less than maximum volumes recommended are used, a more robust and moldable putty will form.

- Sterile Buffered Saline – Introduce the provided saline, normal saline or water for injection to the dry powder, stirring until completely hydrated in a putty form. This step should take no more than one minute.
- For more robust handling, blood may be used in place of the buffered saline.



5

Implantation

- Remove the resultant putty from mixing jar. Put into gloved hand and squeeze, condensing the bolus of graft to tightly bind all constituents.
- Mold into desired shape and apply directly to the surgical site.
- Optecure may be put into a sterile syringe for delivery to the surgical site.

- Optecure and Optecure+ccc may be hydrated with different diluents: whole blood, water for injection, normal saline or provided buffer saline (PBS).
- Optecure and Optecure+ccc is delivered with the maximum amount of PBS.
- Optecure, when mixed with reduced volumes of diluent, may become too robust for syringe delivery to surgical site.
- Optecure and Optecure+ccc remain formable yet resistant to lavage.¹

- Optecure and Optecure+ccc are delivered dry in a mixing jar for quick and convenient hydration. It is recommended that hydration and mixing occur in the provided jar.
- Optecure and Optecure+CCC are not intended for use alone or with bone marrow only in spinal applications.
- Optecure and Optecure+CCC are not intended for use with other allograft in spinal applications.

1. Data on file at Exactech, Inc.