

1.0 Purpose

- 1.1 The purpose of this Standard Operating Procedure (SOP) is to define the requirements for the Callisto™ Granules β-TCP IFU insert.

2.0 Associated Documents

- 2.1 FRM 23-000 (*IFU Generation Form*)

3.0 Specifications

- 3.1 Dimensions/Layout: See Attachment I
- 3.2 Content: Appendix I
- 3.3 Part Number: 27-006

4.0 Printing Callisto Granules β-TCP IFU

- 4.1 Obtain FRM 23-000 (*IFU Generation Form*).
- 4.2 Print one copy of the IFU Attachment and inspect against the clear overlay copy of the IFU to assure it is identical.
 - 4.2.1 An electronic copy of the IFU is stored on the electronic drive with the specification.
 - 4.2.2 Verify IFU is in the English language.
- 4.3 Have another person verify that the IFU print off is identical to the IFU Attachment and if so, indicate this by initialing and dating under the verification box on FRM 23-000 (*IFU Generation Form*).
- 4.4 Record which IFU is being printed and the quantity.
- 4.5 Print the IFU, double sided, on a standard 8 ½" by 11" sheet of paper.
- 4.6 Cut the IFU.
- 4.7 Set aside any defective IFUs that may have been poorly cut or otherwise illegible.
- 4.8 Total the acceptable IFUs, and record on the form.
- 4.9 Destroy all defective IFUs.
- 4.10 Neatly stack and organize IFUs and store them in a covered, labeled container in the raw materials accepted area.

4.11 File the completed form in the Callisto Granules β-TCP RM folder.

5.0 Appendix

5.1 Appendix I: Callisto Granules β-TCP IFU Content

6.0 Attachments

6.1 Attachment I: Callisto Granules β-TCP IFU

7.0 Document History

7.1 Revision of 00: Quality Directive #1 change to format

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Appendix I: Callisto™ Granules β -TCP IFU Content

Callisto™ Granules β -TCP Instructions For Use

Material

Callisto™ Granules β -TCP is a synthetic bone graft substitute in particulate form composed of beta-tricalcium phosphate (β -TCP). The particulate is micro porous and macro porous.

Properties

Callisto Granules β -TCP is osteoconductive. The biocompatibility of beta-tricalcium phosphate is well established. Beta-tricalcium phosphate is gradually resorbed and replaced by vital bone during bone remodeling.

Indications for use

Callisto Granules β -TCP is a resorbable bone void filler intended to fill bony void or gaps of the extremities, posterolateral spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure.

Contraindications

Do not use in clinical situations where orthopedic surgery should not be performed.
Do not use in uncontrolled infection.
Do not use in patients with known allergy or hypersensitivity to material components.

Precautions

Callisto Granules β -TCP should only be used by licensed physicians trained in the use of bone graft substitutes.
Callisto Granules β -TCP should not be used in applications other than those indicated.
Callisto Granules β -TCP is not indicated to be used in immediate load bearing applications.
Do not use in patients with systemic disorders resulting in poor wound healing.
Do not use in site during or after irradiation.
Do not use in the presence of acute or chronic inflammation.
Do not use in infected or compromised tissue sites.
Do not use in hypercalcemic patients.
Do not use where mucosal and bone healing are impaired.
Do not use in immunosuppressed patients.
Do not use in patients on medication inhibiting healing process.
Possible adverse reactions include, but are not limited to: inflammation, infection, fistula formation, extrusions, hematoma, seroma, induration formation, inadequate healing, skin discoloration, and inadequate or excessive augmentation.
Do not use if packaging has been damaged or opened.
Do not overfill defects.
Do not leave defect open.
Single use only. Do not re-sterilize.
Safety in pregnancy and pediatrics has not been established.

Directions for use

1. Remove the outer package Tyvek lid and drop primary package onto the sterile field.
2. Remove Tyvek lid from the primary package.
3. Mix Callisto Granules β -TCP with sterile physiological solution or with the patient's blood.
4. Gently fill each defect to the highest level of bony defect. Do not overfill. Do not compress Callisto Granules β -TCP into the site. Callisto Granules β -TCP will not set like cement.
5. After placement of Callisto Granules β -TCP, ensure primary closure of the soft tissues over the graft site.

Storage

Callisto Granules β -TCP should be kept in original packaging and stored at room temperature in a dry place. Do not use after expiration date.

Availability

Callisto Granules β -TCP is available in single use sterile packaging containing 5 cc, 10 cc, 20 cc or 30 cc of porous granules sized 1000-2000 micron or 2000-3350 micron.

WARRANTY

Cytophil warrants that reasonable care has been exercised in the design and manufacture of this product.
THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ITS PARTICULAR PURPOSE.

Manufactured by: Cytophil, Inc.
Distributed by: Vivex Biomedical, Inc.

CallistoGranules β -TCP is a proprietary product of Cytophil, Inc.

To place an order, please contact customerservice@vivexbiomedical.com

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P/N 27-006 00

R ONLY CAUTION: Federal law restricts this

device to sale by or on the order of a
licensed healthcare practitioner



Temperature
limitations



Do not reuse

STERILE R

Sterilized using irradiation

CAUTION: Consult accompanying
documents



Product contains no detectable latex

REF

Catalog number



Manufacturer

LOT

Batch number



Use before

COPY