The safety and effectiveness of this device for use in osteochondral defects has not been established.

Device Description
The Smith & Nephew TRUFIT™ Bone Graft Substitute (BGS) Plug is manufactured from POLYGRAFT® material, a blend of poly DL-lactide-co-glycolide, calcium sulfate, polyglycolide fibers and surfactant. This product is supplied sterile for single use only. The POLYGRAFT material is provided as granules, small cubes, porous blocks, and preformed plugs in a variety of sizes. When used according to the Instructions for Use, the material degrades in approximately 4–8 months.

Contents
The TRUFIT™ BGS Plugs are provided as a kit and contain one of each of the following:

- Cylindrical implant
- Delivery device (outer sleeve and measuring tamp)
- Trimming knife

Indications for Use
TRUFIT BGS Plugs are indicated for use in filling bony voids or gaps caused by trauma or surgery that are not intrinsic to the stability of the bony structure. TRUFIT BGS Plugs are indicated to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, spine and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. TRUFIT BGS Plugs provide a bone void filler that resorbs and is replaced with bone during the healing process.

Contraindications
TRUFIT BGS Plugs are not intended to provide structural support during the healing process, therefore, they are contraindicated where the device is intended as structural support in the skeletal system.

Conditions representing relative contraindications include:

- Known hypersensitivity to the implant material. Where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.
- Severe vascular or neurological disease.
- Uncontrolled diabetes.
- Severe degenerative bone disease.
- Pregnancy.
- Presence of infection at the site.
- Uncooperative patients who will not or cannot follow postoperative instructions, including individuals who abuse drugs and/or alcohol.
- Hypercalcemia.
Warnings

- Contents are sterile unless package is opened or damaged. DO NOT RESTERILIZE. For single use only. Discard any open, unused product. Do not use after the expiration date.
- Do not use this device if pouch has been opened, damaged, or temperature dot indicator on package has turned black.
- It is the surgeon’s responsibility to be familiar with the appropriate surgical techniques prior to use of this device.
- Read these instructions completely prior to use.
- As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes individuals with bleeding disorders of any etiology, long-term steroidal therapy, or immunosuppressive therapy.
- After use, this device may be a potential biohazard and should be handled in accordance with accepted medical practice and applicable local and national requirements.

Adverse Reactions

Possible adverse reactions include but are not limited to:

- Wound complications including hematoma, site drainage, infection, bone fracture, and other complications that are possible with any surgery.
- Fracture or extrusion of the TRUFIT® BGS Plugs, with or without generation of particulate debris.
- Deformity of the bone at the site.
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler.

Instructions for Use

Use TRUFIT BGS Plugs aseptically according to the following surgical technique:

For placing TRUFIT Plugs, shape implants if necessary and insert to snugly fit into defect site. Avoid overfilling the bone void or compressing the treatment site. Ensure that the entire treatment site is filled and is in direct contact with well-vascularized tissue. Remove excess material from the site. Close the site using standard closure techniques. Discard any unused TRUFIT BGS Plugs.

Use of TRUFIT Delivery Device System:

1. To assemble the TRUFIT Delivery Device, insert the measuring tamp into the outer sleeve in the direction of the arrow on the outer sleeve until contact with the preloaded implant is made.
2. At this point, the implant should not extend beyond the delivery device.
3. Insert the measuring tamp of the delivery device into the defect assuring that it contacts the bottom of the defect.

4. Slide the outer sleeve down until the lip of the outer sleeve is snugly placed against the surface of the tissue (this automatically adjusts the implant to the correct position for trimming), then carefully remove the delivery device from the surgical site.

5. Firmly grip the outer sleeve at the windows to secure the implant during cutting. Steady the hand and delivery device against a table or other sterile surface. Using the lip of the delivery device as a guide, cut the notched end of the implant with the trimming knife using a firm downward motion.

Note: Caution should be taken not to nick the top of the outer sleeve of the delivery device.

6. Once the implant has been cut to a flat surface, the delivery device is used to insert the implant into the defect. Slightly advance the implant beyond the tip of the outer sleeve.

7. Carefully seat the implant in the defect and press fit into the defect by pushing on the measuring tamp manually or lightly tamping with a mallet. Remove the delivery device from the surgical site.

8. If the implant needs further adjustment or contouring, separate the measuring tamp from the outer sleeve and use the tamp to impact the implant. The final placement of the implant should be flush with the adjacent surface.

Storage Conditions

⚠ Warnings

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- Do not use this device if pouch has been opened, damaged, or temperature dot indicator on package has turned black.

This material is temperature sensitive. Store between -20 to 30° C (-4 to 86° F). Exposure to temperatures above 60° C (140° F) should be avoided.

Warranty

For single use only. This product is warranted to be free from defects in material and workmanship. Do not reuse.

For Further Information

If further information on this product is needed, please contact Smith & Nephew Customer Service at 1-800-343-5717 in the U.S., or your authorized representative.