

ortho**PLUG**<sup>®</sup>  
Soft Bone Kit II



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# orthoPLUG® | Soft Bone Kit II

## The orthoPLUG® Soft Bone Kit II contains:

- ◆ **Canal Restrictor**
  - Small, Medium & Large orthoPLUG®
  - Insertion Instrument
- ◆ **Canal Preparation Tools**
  - Canal brush
  - Canal packing
- ◆ **Alignment Guide**
  - Anteversion Gauge
- ◆ **Cement Removal Tool**
  - Two curettes
  - Scalpel

## DESCRIPTION

The orthoPLUG® Soft Bone Plug is a polyethylene canal restrictor designed to prevent distal migration of the cement (methylmethacrylate) in the femoral marrow space during placement of the stem in a total hip replacement. Multiple flexible fins accommodate the irregularities of the canal.

## INTENDED USE

The orthoPLUG® is intended to be used as part of cementing the femoral component in total hip surgery. The orthoPLUG® is placed distal to the stem to restrict the cement and to augment pressurization of the cement column.

This device is to be used by a surgeon well trained in total hip surgery and with a working knowledge of the anatomy of the femur.

## CONTRAINDICATIONS

The orthoPLUG® is not designed or intended for any use except as indicated. The orthoPLUG® should not be used when the femoral bone is so damaged from disease or trauma, that the placement of the plug would result in further damage to the femur or that the plug would be ineffective in its intended function.

The orthoPLUG® should not be used in the presence of infection, sepsis or osteomyelitis. Severe osteoporosis represents a relative contraindication as the plug may not function well and insertion could damage the bone. The

orthoPLUG® should not be used if the patient is allergic to polyethylene.

## WARNING

The orthoPLUG® Soft Bone plug should be sized and applied properly. Improper placement, selection or positioning may result in ineffective function of the device or damage to the femur. The device needs to be used in conjunction with proper and appropriate cementing techniques. Only a qualified medical professional should place the orthoPLUG®.

## PRECAUTIONS

This product has been sterilized by irradiation and should not be used if the packaging has been damaged. Sterilization by autoclave is not recommended for the orthoPLUG® as it will damage the device. All the components of the orthoPLUG® Kit II are one time use only – **DO NOT REUSE.**

The sizing guidelines are approximate, the optimal size may need to be determined at the time of surgery. As outlined below, on occasion this device may not be effective and a different method of plugging the canal must be used.

## STERILITY

This product has been sterilized by irradiation. DO NOT re-sterilize with steam autoclave as this will damage the orthoPLUG®. The disposable Insertion instrument has been sterilized by irradiation and should be discarded after use. **DO NOT USE IF PACKAGE HAS BEEN DAMAGED.**

## CAUTION

Federal law restricts this device to use by or on the order of a physician.

## INSTRUCTIONS: Canal Restrictor

1. The appropriate sizes of **orthoPLUG® Soft Bone Plug** is determined by one of two methods. If the canal diameter at the level of insertion is known (in millimeters) then the following chart can be used. Canal sounds or canal reamers, not included as part of the **Soft Bone Plug** instruments, can be used to determine the size at the desired location.

Size	Canal Range	Central Ring
Small	11-15 mm	11 mm
Medium	14-18 mm	14 mm
Large	17-22 mm	17 mm

A trial method can be used with the **Soft Bone Kit II** where all three sizes are available. Start with the smallest size and increase the plug size based upon the firmness of fit. The fins are flexible and forgiving but the wide central ring of the **Soft Bone Plug Soft Bone Plug** is not flexible. If marked resistance is encountered before the plug is in the desired position, remove the plug and replace with a smaller size. The **Soft Bone Plug** can be **lightly** malleted into position, but this is not advisable in weak or osteoporotic bone. If the plug becomes stuck the insertion tool threads may not be strong enough to remove the plug. If this happens, the extraction tool (not included in this kit) can be used.

The stainless steel insertion instrument was designed for single use and is part of the **orthoPLUG® Soft Bone Kit II**. The markings on the instrument can be used to determine the desired placement of the plug.

2. Place the **orthoPLUG® Soft Bone Plug** on the threaded end of the insertion tool. **Lightly** tighten, as the threads may strip and the holder will need to be unthreaded after placement of the plug.
3. Determine the level that is desirable (usually about 2 cm distal to the tip of the femoral component). The instruments are marked at one centimeter intervals.

4. Clean and **SUCTION** the canal so that the contents won't be compressed with plug insertion. Place the plug into the clean dry canal.
5. When the plug is at the desired level and if there is good resistance to the distal force, then remove the insertion instrument by gently unthreading it.
6. If there is unsatisfactory resistance then push the plug about two centimeters past the desired placement location and then pull it back to the desired location. This flips the distal fins from a proximal to a distal direction and will result in increased resistance to distal pressure.
7. If there is unsatisfactory resistance to distal pressure - use a larger plug. If there is still unsatisfactory resistance, use the largest plug. If none of the three plugs work, then use a different means of restricting the canal.

## INSTRUCTIONS: Canal Preparation

1. Clean loose debris from the proximal femur.
2. The canal brush is used to remove loose bone, marrow and blood clots. This is accomplished with an in and out motion in combination with rotation.
3. Lavage the canal (not part of the **orthoPLUG® Kit**).
4. Suction the canal so that it is free of irrigate and blood.
5. Using the **orthoPLUG®** insertion instrument, push the canal packing to the canal restrictor. Continue pushing the canal packing into the marrow space with the **orthoPLUG®** insertion instrument until the marrow space is full.
6. Pull the packing from the canal, cut off the used portion and pack a second time in a similar fashion.
7. Remove the packing and if the canal is dry then it is ready for cementing.

## INSTRUCTIONS: Alignment Guide

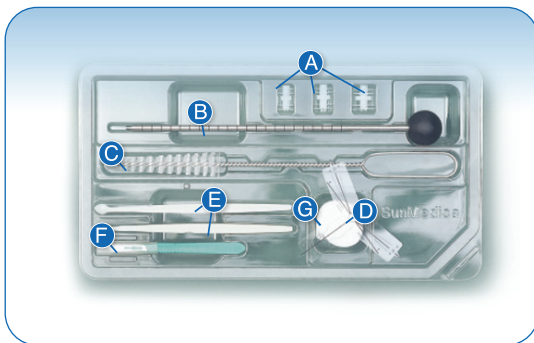
1. Place the **Insertion Instrument** through the hole in the anteversion alignment guide.
2. Most total hip replacement stems have a hole or depression that is in line with the long axis of the stem and in the center of the marrow canal once the prosthesis is in place. If no such landmark exists then estimate the longitudinal axis of the stem. Place the distal end of the **orthoPLUG® Insertion Instrument** into the hole or depression then align the **Insertion Instrument** with the axis of the femur (stem). Align the foot marking on the **Alignment Guide** with the patients' leg. The neck portion of the stem is examined through the transparent guide to determine the approximate degrees of anteversion.

## INSTRUCTIONS: Excess Cement Removal

1. While the **cement** is still doughy, use the **scalpel** to cut the excess cement from the parameter of the stem where it inserts into the bone. It is best to cut the cement away rather than to scrape it away so that the cement is not pulled from the cement bone or cement metal interface.
2. Use the **curettes** to remove the excess cement once it has been cut.

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catalog on our online store!  
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ortho**PLUG**®



**Soft Bone Kit II**  
ORDER# OP-SB-Kit II  
\$194.00

- A** ortho**PLUG**® (small, medium, large) canal restrictors
- B** Insertion Instrument
- C** Canal Brush
- D** Alignment Guide (Anteversion Gauge)
- E** Large/Small Curettes (cement removal)
- F** Scalpel (cement removal)
- G** Canal Packing (cement)

*For more information, please contact us  
and we will be happy to assist you.*



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