



## Parcus Tibial Plug Important Product Information Directions for Use

### 1. Indications:

Parcus Tibial Plugs are used during ACL/PCL ligament repair or reconstruction procedures to limit the loss of irrigation fluid from the knee joint. The Parcus Tibial Plugs are supplied in two configurations; solid and with a 2.4mm cannulation. Both designs are tapered to accommodate tunnels from 7mm to 12mm in diameter.

### 2. Warnings:

- A. This product is intended for use by or on the order of a physician.
- B. Do not use this product if it shows any visible signs of damage.
- C. This device is not intended to be used to dilate the tibial tunnel. Care should be exercised when placing the plug to prevent fracture of the proximal tibia.
- D. This device is not intended to be used as an implant.

### 3. Material:

This device is comprised of PEEK, is radiolucent, and may be visualized through the use of ultrasound or MRI.

### 4. Inspection:

- A. Inspect the device for damage at all stages of handling.
- B. If damage is detected, consult the manufacturer for guidance.

### 5. Cleaning:

- A. Immediate rinsing and cleaning after use with an enzymatic detergent will effectively remove and prevent drying of adherent blood, tissue, etc.
- B. Scrub device with a soft brush, paying special attention to areas where debris might accumulate. Always avoid any harsh materials that can scratch or mar the surface of the device.
- C. Rinse the device thoroughly with water following the cleaning process.

### 6. Sterilization:

See following table for recommended minimum sterilization parameters that have been validated by Parcus to provide a  $10^{-6}$  sterility assurance level (SAL).

Cycle Type	Min Temperature	Min Exposure Time (Wrapped)	Min Dry Time
Gravity	132°C / 270°F	15 minutes	30 minutes <sup>1</sup>
Pre-vacuum	132°C / 270°F	4 minutes	

Drying times vary according to load size and should be increased for larger loads.

### 7. Directions for use:

- A. Create a tibial tunnel that is 7mm to 12mm in diameter.
- B. If a guide wire is present in the tunnel, select the cannulated version of the Parcus Tibial Plug. The cannulation is 2.4mm in diameter. If no guide wire is present, the non-cannulated Plug can be used.
- C. Gently press the tapered end of the Plug into the tunnel until an interference fit, sufficient to keep the Plug in place, is achieved.
- D. Remove the Plug to pass instruments, graft material and suture.
- E. Replace the Plug, described in Step C, as necessary.

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