

# God's Hand Instructions For Use

## HOW SUPPLIED

The God's hand is supplied sterile and intended for one-time use. In the event of damage to the sterile packaging, do not re-sterilize the product.

## DESCRIPTION

The God's hand is a pneumatic compression device for femoral arteriotomy hemostasis which is a single-use, disposable and consists of a cruciform main body and four pieces of supplementary tape. The main body has a self-adhesive peel backing and a semi-compliant inflatable bulb (4 cm in diameter) under a transparent plastic dome at the center of the body and supplementary tapes also have a self-adhesive peel backing.

## INTENDED USE

The God's hand is an external compression device which involves a small inflatable balloon or bulb, and compression to the femoral arteriotomy occurs via the pressure exerted by the inflated balloon. The God's hand is being kept in place and exerts pressure to maintain hemostasis for the entire duration of the compression so additional pressure dressing is not necessary.

## SUGGESTED INSTRUCTIONS FOR USE FOR THE GOD'S HAND



1) With the sheath in the femoral artery, secure the main body over the puncture site after removal of the self-adhesive backing while positioning the center of the bulb 1cm proximal to the sheath entry site.

**NOTE:** To prevent contact dermatitis, placing gauze under the center of the bulb can minimize the skin side effect at removal of the device.



2-3) Apply four pieces of supplementary tapes over the wings of the main body to

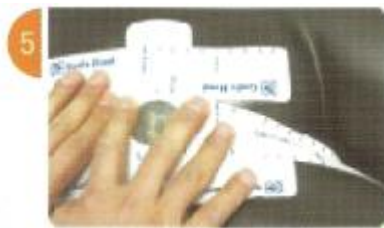
reinforce the attachment of the main body to the skin.



4) Inflate the bulb with room air (approximately 120 cc in volume)

**NOTE:** Appropriate adjustment of the bulb position such that the bulb fits into the groin and exerts maximal pressure on the

arteriotomy site should be of greater importance than additional inflation of the bulb.



5) Keep manual compression over the bulb. Gradually release manual compression over a few seconds under visual inspection for any bleeding below the plastic dome.

## SUGGESTED INSTRUCTIONS FOR USE FOR THE GOD'S HAND

1. The patient should take bed rest for 2 hours after the procedure. The patient can lie down side or bend the legs slightly after 3 hours.

2. After checking any complications related to hemostasis, remove the device from the puncture site 3 hours after the procedure. From this point on, ambulation is possible. Avoid radical movements.

**Note:** When any signs or symptoms of leg ischemia develop during the time of the device application, slowly deflate the bulb until the ischemic signs or symptoms disappear, while maintaining control of bleeding. Confirm hemostasis by viewing the puncture site through the deflated bulb. After hemostasis is successful, lightly re-inflate the bulb with 70–80 ml of room air and return the patient to the ward with the device kept in place.

3.. Check the pulsation of the ipsilateral dorsalis pedis every 30 minutes for two hours and then hourly until the removal of device. (If there is bleeding, re-inflate the balloon.) Check the groin for any bleeding or hematoma formation before ambulation.

4. With elderly patients who have low skin elasticity, patients with severe obesity or general anesthesia, the God's hand should be used very carefully.
5. If pain or persistent oozing of blood is noted, notify the physician immediately.

**Note:** Using of the God's hand can be customized according to the clinical situation and patient characteristics in practice.