

TO WHOM IT MAY CONCERN.

CLINICAL EVIDENCE OF THE PRODUCT : BASKA MASK.

Date: 9th Aug, 2011.

Product description.

Name of Product: 'BASKA MASK'.

Definition:

This is a device used in clinical practice in anesthesia and resuscitation to ensure an airway patency and enable positive pressure ventilation when necessary to maintain oxygenation and at the same time clear all the unwanted materials from the throat to prevent lung aspiration and subsequent complications in a patient.

Description of the product:

The product consists of a mask with an airway cavity and a sump cavity separated by a membrane and a stem with a connector. The mask is attached to the stem which consists of an airway tube and two other tubes that are arranged on either side of the airway tube. The airway cavity of the mask is in fluid communication with the airway tube and the two side tubes are connected to the sump cavity and have fluid communication with each other through the sump cavity. The sump cavity extends at its distal end into the upper end of the oesophagus when positioned correctly in the laryngopharynx and is in fluid communication with the oesophagus. A 15 mm plastic connector is attached to the outer end of the stem to enable the device to be attached to an anaesthesia machine or a resuscitator bag.. The side tubes have separate openings on either side of the airway connector and to which an interchangeable separate plastic elbow can be attached for the use of the suction which will clear the sump area of its contents. Out of the two side tubes, at a given time during the use of the suction , one side tube acts as a vent when the other functions as a suction tube.

PURPOSE OF ITS USE;

The device is intended for use in anaesthesia, resuscitation and intensive care for maintenance of airway.

IN CLINICAL USE AND ITS PERFORMANCE:

Baska Mask is similar in design and function in comparison to the LMA-Classic, which are in clinical practice since 1990.

I have used Baska Mask in manikins and in 50 patients undergoing surgical operations. The Baska Mask performs well in clinical situations in accordance with the intended purpose. It differs from the LMA-Classic (first generation laryngeal mask) that it has two additional tubes to clear the sump cavity of any unwanted materials in the pharynx when a high suction attached to any one of the side tubes. It also differs in design with the presence of an expandable membrane that makes the mask

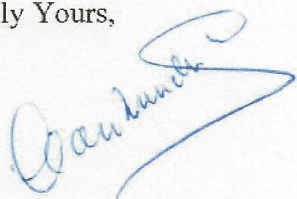
achieve a better seal for ventilation that no other airways currently in use can deliver. It has a pulling Tab that is of great advantage to facilitate easy insertion in comparison to the other airways.

Looking at the literature, I believe in some ways the Baska Mask overcomes the difficulties that some of the previous masks have during their use.

CONCLUSION:

The Baska Mask performs as intended and it is safe to use in indications where normally a LMA-Classic would be used.

Sincerely Yours,



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