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"510(K) Summary" as required by 807.92(C)

Name: Patrick J. O'Regan
Address: 912 - 750 West Broadway
Vancouver, B. C. V5Z 1H8
Ph: (604) 876-9926 Fax: 872-7533

Contact Person: Patrick J. O'Regan

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Common Name: Hemorrhoid Ligator

Proprietory Name: O'Regan Ligator

Description: The O'Regan, Ligator or Hemorrhoid Ligator is a device for the treatment of hemorrhoids. The treatment of hemorrhoids by elastic band ligation is credited to Blaisdell who described the technique in the late 1950's, and in the early 1960's Barron popularized this treatment after his reports in the medical literature. The technique involves placing elastic bands on tissue in the rectum in the vicinity of the hemorrhoids. The bands are placed high enough in the rectum to be above the sensitive area so that any discomfort from the procedure is minimized.

A number of different devices have been available to date. Some of the devices such as the Goltner Ligator rely on a suction technique to draw the tissue into the chamber and an expanded elastic band is placed around the trapped tissue in the chamber thus cutting off it's blood supply and causing the tissue to necrose. The resultant healing proves beneficial and helps to shrink hemorrhoids and restore the anatomy towards normal configuration. Other devices such as the McGivney Ligator are used in conjunction with a forceps which is used to draw tissue into the chamber before banding.

The present device provides suction and ligation capability. An elastic band can be stretched over the front end of the ligator by means of the cone shaped loading apparatus. The front end of the ligator is inserted through the anus deep within the rectum. The nozzle is then withdrawn gently as the device is angulated to point directly towards the site to be banded. The site to be banded will have been previously identified by means of examination with a sigmoidoscope, a proctoscope or such an instrument. A mark on the outside of the device will provide a measure as to the level inside the rectum where the band is to be placed. Thus by angling the device acutely in the direction of the tissue to be banded and by measuring the distance from the outside, the band can be placed accurately on the appropriate tissue.

The opening at the front end of the device allows only a fairly conservative amount of tissue to be trapped within the chamber and subsequently allow banding of this said amount. The aperture has been found by trial and error to be optimal and conservative. This aperture is in fact smaller than that used on any of the other hemorrhoidal ligators available on the market. This ligator is intended to be used only as a hemorrhoid ligator. This device differs mainly in one respect from other devices available to date. Whereas other devices are designed to be used with the aid of a proctoscope or similar viewing instrument and the band is placed under direct vision, the present device is designed to be used without a proctoscope. As mentioned above the site to be banded is initially identified by inserting a viewing device such as a sigmoidoscope or proctoscope. The present device does not require that a proctoscope or anoscope be used in conjunction with the device.

As can be seen from the summary of the clinical data provided, the bands can be placed as accurately or more accurately by this technique. The size of the bite of tissue banded is also more constant and more precise than with other methods. If the band for some reason is not optimal, it can be fairly readily displaced with the examining gloved finger. The device can be used single handedly, as a proctoscope or an assistant is not necessary to perform the procedure.

The device will be made available in a package, labelled clean but not sterile for one time use only. Rubber bands will not be included but are readily available from medical suppliers. The device will be produced by Columbia Plastics Ltd. Custom Injection Molding, 19320-60th Avenue, Surrey, B. C. V3S 8E5. The device is made of polypropylene with no colour additive.

I hearby certify that, in my capacity as owner and developer of the O'Regan Ligator, I believe to the best of my knowledge, that all data and information submitted in the premarked notification are truthful and accurate and that no material facts have been omitted.

_____(Signature)

_____(Name)

_____(Date)

_____(Premarket Notification 510k Number)