

Product Bulletin

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Date: **AUGUST 15, 2014**

RE: PULL THRU™ Channel Cleaning Device versus generic references to channel cleaning brushes.

The purpose of this product bulletin is to provide clarification related to the use of PULL THRU Channel Cleaning Devices sold by MEDIVATORS compared with a generic reference to channel cleaning brushes.

It is important to understand the history regarding manufacturer's IFUs and those recommendations of the guidelines issued by the professional bodies that represent cleaning and disinfection of flexible medical endoscopes.

At the time flexible medical endoscopes became a popular medical diagnostic tool, manufacturers designed, marketed and recommended their own range of cleaning "brushes". This was primarily driven by the fact that there were not "off the shelf" cleaning brushes available and that each endoscope manufacturer validated their own manual cleaning process using these brushes. This philosophy has remained to the present day.

With the introduction of so many single use and disposable endoscope accessories and cleaning devices, it is difficult to know how and when to consider the use of devices other than those sold by the endoscope manufacturer. One must also consider that there is a strong marketing influence by the endoscope manufacturer to prevent the use of competitive devices that is not based on safety and efficacy.

It is important that the choice of alternate cleaning device is based on sound evidence that the product will meet the requirements of the endoscope type (channel length and diameter) and will not cause damage to the channel system. This information needs to be provided by the cleaning device distributor as well as any other source of information sharing.

The verbiage used by the endoscope manufacturer needs to be studied carefully to fully understand the impact of using alternative devices for the manual cleaning steps. All endoscope manufacturers recommend the use of their brushes, but do not include verbiage that categorically contradicts the use of other products.

MEDIVATORS has used PULL THRU Channel Cleaning Devices during many of their validation studies and have found that it out performs the use of bristle brushes in all applications especially those where biofilm is found.

In summary, there are no regulatory reasons that endoscope users should not deviate from the recognized norm where the use of alternative devices can improve the standards of reprocessing. Changes should be based on an informed decision that encompasses the benefits as well as the potential pitfalls associated with the change.

MEDIVATORS, as one of the leading companies involved in infection prevention products as well as the leader in endoscope reprocessors, fully stands behind the PULL THRU Channel Cleaning Devices that they provide and can provide support and assistance to any customers considering using these products.

If you have any questions related to this product bulletin contact MEDIVATORS Customer Support at 1-800-444-4729 or contact your authorized MEDIVATORS representative.

PULL THRU™ is a trademark of F.R. Galantai Manufacturing Company Limited.



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