HEALTHY EARS, BETTER HEARING

OFF-LABEL EQUIPMENT INFORMATION

Microsuction Machine Risk Assessment

Suction units used for microsuction must have a CE Marking that certifies they meet the legal requirements for safety, quality and performance when they are used as the manufacturer instructs. Manufacturers have generally designed their suction equipment for oral and tracheal usage. Some manufacturers describe their machines as a 'bodily fluids' suction device. At present, no machine has been specifically designed for aural micro-suction, and thus no machine has been CE marked specifically for this purpose. intended use for aural microsuction.

However, the National Institute for Health & Care Excellence (NICE) specifically recommends microsuction for ear wax removal. It is implicit in this recommendation that suitable equipment must be available. Unfortunately, the CE research bodies have not yet investigated aural microsuction using of these "off-label" devices, i.e. outside the manufactures instructions. There are no standards to measure their performance/risk of suction when used aurally. At there are inherent risks to performing any kind of ear wax removal, a cautious approach is the best option.

The Medicines & Healthcare products Regulatory Agency (MHRA) have advised as follows:

> *"Although rare, it is possible that there is no medical device available for a procedure. In this case you should decide whether to use an existing medical device for a different purpose,* ***modify a medical device for a new purpose*** *or use a product for a medical purpose that is not CE marked as a medical device".*

To use the existing machines for aural microsuction, It Is necessary to add specific narrow suction tubes, As the intended use of medical suction pumps was never to remove ear blockages, in our view, and in the view of The Hearing Lab™ which supplies the medical suction machine used by EssexEars, we are modifying an existing medical device for a new purpose and are thus within the guidance of the MHRA. In such cases, the MHRA guidance is as follows:

> *A balance between the risks and benefits to the patient must be considered and if necessary, some recommendations made. Some points are:*
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> - *carrying out a risk assessment and documenting it*
> - *considering the ethical and legal implications*
> - *implementing suitable precautions to minimise the risk*
> - *reviewing the risk assessment at suitable periods*
> - *getting approval from MHRA for exceptional use of non-complying devices (if necessary)*
>
> ***You must inform the patient during the consent procedure and make a note on their records that you will be using a medical device off-label.***

To address this last point, we have created a digital consent form. Please feel free to bookmark it and use it as often as you like.

The Hearing Lab™ has also created a risk assessment template that contains the main probable risks, knows to them. It will be adjusted or added to by them and by EssexEars to take into account any changes in the risk profile, including any new risks encounter during clinical practice. However, as any risk assessment must be individual, at the assessment stage EssexEars will assess whether there are any additional or heightened risks that are particular to a given patient.