DTR MEDICAL QUALITY SYSTEM DOCUMENT

Title:	
Tympanostomy Mould Directions For Use	
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COVER SHEET

Issue No.	Date of Issue	Originator	Amendments/Justification
01	05/06/2103	K. Gittins	Introduction of new document to accompany tympanostomy product. QMSDC094-13
02	14/06/2013	K. Gittins	Update made to temperature as requested by customer and verified by S. Richards. QMSDC 101-13

DESCRIPTION

Fasciaform Tympanoplasty Mould

The Fasciaform Tympanoplasty Mould is intended for use in formaldehyde-formed fascia grafts or in the fasciaform graft technique to provide an effective method of closing large tympanic membrane perforations, subtotal tympanic membrane perforations and total tympanic membrane perforations with excellent functional results and minimal complications. The formaldehyde-formed fascia graft represents another step toward more reliable functional restoration of the intact tympanic membrane.

This procedure is associated with high rates of tympanic membrane closure. Its primary indication is in tympanic membrane perforations with an intact malleus although the concept can be employed in conjunction with various types of ossicular reconstruction.

The clinical procedure was developed by Rodney Perkins.
(Ref: *Trans Sect Otolaryngol Am Acad Ophthalmol Otolaryngol*. 1975 Nov - Dec; 80(6): 565-72. "Formaldehyde-formed autogenous fascia graft tympanoplasty").

INDICATIONS FOR USE:

For use as a mould to enable formaldehyde-formed autogenous fascia graft tympanoplasty

DIRECTION FOR USE:

This procedure is only to be carried out by qualified personnel who have the expertise in formaldehyde-formed autogenous fascia graft tympanoplasty.

DEVICE DECONTAMINATION:

The Left and Right Fasciaform Tympanoplasty Moulds are supplied sterile by DTR Medical Ltd, having been sterilized by irradiation. The devices are suitable for reuse if they are effectively decontaminated between each clinical procedure.

The instruments are made of surgical instrument-grade stainless steel and will be long lasting if handled, cleaned and sterilized in accordance with the Manufacturer's reprocessing instructions detailed below.

PRE-CLEANING: Remove any gross debris from the device using water and a swab or sponge immediately following the procedure to prevent blood and body fluids drying onto the device.

It is important to adequately rinse instruments immediately after use to prevent bodily fluids drying onto the device since they will be more difficult to subsequently remove if allowed to dry; saline solutions may also be corrosive to the stainless steel.

If pre-cleaning or cleaning cannot be undertaken immediately after use the device should be kept in a moist environment to prevent bodily fluids drying onto the device

CLEANING: The instrument should be subject to a low temperature ultrasonic prewash using an enzymatic detergent. Immerse the fully opened and/or disassembled instruments in a neutral pH enzymatic detergent, suitable for use with surgical instruments. Prepare the solution and use in accordance with the manufacturer's recommendations, paying attention to the detergent dilution and immersion time and temperature.
The use of an ultrasonic cleaner assists in the removal of soil from hard to reach surfaces.

If an ultrasonic bath is not available the instrument may be manually pre-cleaned in a solution of neutral pH detergent appropriate for cleaning surgical instruments, used in

accordance with the manufacturer's instructions. When manual cleaning, do not use steel wool, wire brushes, scalpel blades or highly abrasive cleansers to remove soil from instruments

After the prewash remove the instrument from the enzymatic detergent and rinse thoroughly in deionised water or sterile water.

Following the prewash the instrument should then be subject to thermal disinfection using an automatic washer-disinfector. This should be undertaken in a Washer-Disinfector, such as those described in EN 15883, using a pH neutral or enzymatic low-foaming detergent and rinse-aid validated in accordance with manufacturer's instructions.

Load the device such that lumens and holes can drain. Ensure any concave surfaces are pointing down to prevent pooling of water. Where available use an appropriate cannulated instrument rack with attachments to flush the inside of lumens and cannula.

Run standard instrument cycle, with a minimum 5-minute cold wash (<35°C) and an initial 3-minute rinse.

The final rinse/disinfection should exceed 80°C for 10-minute, 90°C for 1-minute (or provide thermal disinfection with an A0 of ≥ 600). Final rinse water should be of high purity and controlled for bacterial endotoxins.

When drying is achieved as part of the washer-disinfector cycle, do not exceed 130°C.

After cleaning visually inspect the instrument for cleanliness and ensure all parts are in working order. If any soil or fluid is still visible, return the instrument for repeat decontamination. Particular care should be taken in the inspection of cannula, lumens or blind holes.

Before instruments are packaged or wrapped for sterilization they must be thoroughly dry.

PACKAGING: Instruments should be packed in a suitable sterilization packaging material (see EN 868), such as polyethylene/paper pouches, and sealed in accordance with the supplier's instructions. Ensure that the pouches are large enough to contain the instrument without stressing the seals.

STEAM STERILIZATION: Following cleaning and packaging the reusable instruments are ready for sterilization.

Sterilize by moist heat (steam) using a Porous Load (Vacuum) Steam Sterilizer, such as those described within EN 285, at 134 -137°C for 3 to 3½ minutes.

Allow the instruments to cool before use.

STORAGE: Instruments should be stored in a cool (<25°C), dry environment after sterilization.

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