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To Whom It May Concern

OtoSwab Accreditation

The dangers of material lint in surgery are well known. Many complications and reactions result from particulates like lint, in surgical wounds. Foreign bodies of lint can result in a granuloma or adhesion formation. We can all be proactive in reducing particulates in the operative field. Some of these ways are to use lint-limiting materials throughout.

This situation is no different in surgery of the lateral skull base, particularly Middle Ear Surgery. For decades, manually rolled micro balls of lint containing cotton wool have been used both as a surgical tamponade and as a mode of delivery for medicated solutions to the cavity of middle ear. Because, no alternative higher quality surgical device has been available.

Recognising the limitations of using lint containing micro cotton wool balls in this surgery, Mr. Balman identified that Kettenbach GmbH & Co. KG had the ideal material of manufacture and the engineering expertise to manufacture a surgical device of a different design to the highest standards.

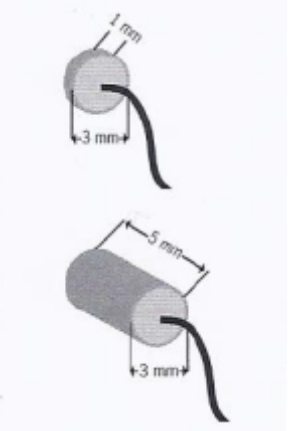
Kettenbach GmbH & Co. KG. is the Medical Divisional branch that has a more than a 60 year experience in the production of a virtually lint-free material made of pure cotton and regenerated cellulose (Sugi®) . Because of Kettenbach's revered pedigree of the manufacture of stable high quality medical materials, that Mr. Graham J. B. Balman (Clinical Director NEOMEDICAL, South Africa) approached Dr. Enyinnaya Okpara (Head Kettenbach Medical, Germany) with the design of a new novel surgical device for the use as a tamponade due to its hydrophilic expansion values and as a delivery system of medicated solutions to the cavity of middle ear during surgery of the lateral skull base.

The brief supplied by Mr. Balman included the following principals;

- The surgical device to be highly absorbent
- The surgical device to have high tensile strength properties making it virtually lint free
- The surgical device to be connected to a safety tether for quick identification and safe retrieval.

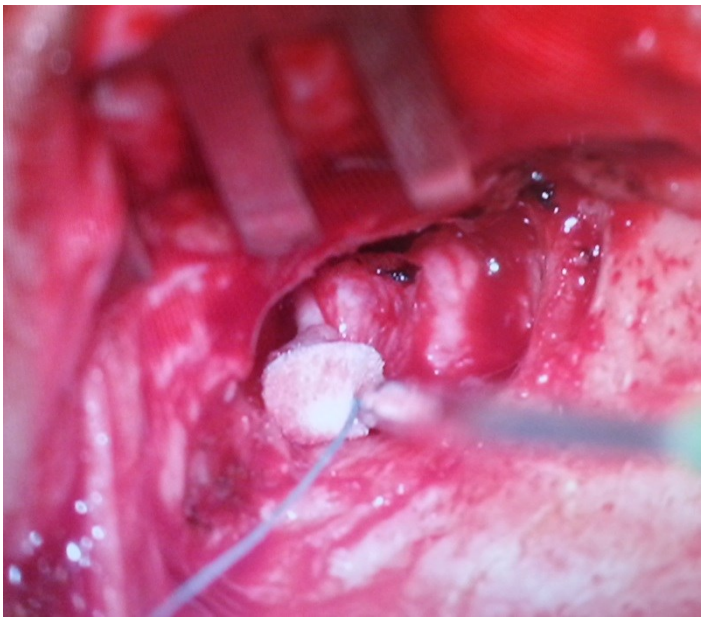
Under the dedicated guidance of Dr. Okpara, the surgical device, now known as OTOSWAB, of Mr. Balman's design idea was manufactured within the given parameters of the Sugi® material and of course with Kettenbach experience from the fields of ophthalmology, ENT, diagnostics, micro surgery, dentistry, etc. Kettenbach mastered the challenge of securely attaching a retrieval cord to a Ø 3mm sponge disc. This resulted in a unique device with the following characteristics:

- OTOSWAB is manufactured from Sugi® sponge hydrophilic material with an absorptive capacity that ranges from 1200% - 2100%.
- OTOSWAB is manufactured from Sugi® sponge material made of pure cotton and regenerated cellulose is virtually lint-free. The tensile strength (tear strength) expresses the bonding of the cellulose sponge material with the regenerated cellulose (> 50 N). The hydrophilic property is based on open pore structure, cellulose affinity to water, adhesion, cohesion and van der Waals forces.
- OTOSWAB is connected to a 21cm strong bright green cotton tether for quick in situ identification and safe retrieval from the surgical site.
- OTOSWAB has a diameter of 3mm, and 1mm thickness in the dehydrated state. The OTOSWAB presents with a diameter of 3mm, and a 5mm thickness in its hydrated state.



1. Diagram to show dimensions of OTOSWAB.

The result of this collaboration between Mr. Balman's idea and the high surgical device engineering and manufacturing capacity of the Medical Division of Kettenbach GmbH & Co. KG under the dedicated management of Dr. Enyinnaya Okpara, is a surgical device (OTOSWAB) that will make for the need of micro tamponading and delivery of solutions in lateral skull base surgery, safer.



2. **Photomicrograph to show OTOSWAB as used to deliver vasoconstrictive solution to tamponade bleeding during a surgical procedure on the lateral skull base.**

OTOSWAB also describes the collaboration between two professionals of two different countries where borders are neutralised in the collaboration for a common end purpose to increase the safety of healthcare.

Kettenbach GmbH & Co. KG

ppa. Enyi Okpara
Head Kettenbach Medical