

SM Synergy Medical Corporation

Will a SU-POR Ear Implant harden with age or become more brittle?

Historical data on the use of porous polyethylene (HDPE) implants show no reported occurrences of implants hardening or becoming more brittle with age.

If the SU-POR Ear Implant breaks or fails, can it be fixed, or will the ear have to be cut off?

If a SU-POR Ear Implant breaks or fails, a surgeon can replace the implant with a new SU-POR Ear Implant using the proper surgical techniques for which they are trained. If there is an active infection in the area, a new SU-POR Ear Implant should not be used until the infection has resolved.

Will the use of a SU-POR Surgical Implant work with other facial anomalies?

Yes, Poriferous provides an extensive family of SU-POR products designed in sheets, blocks, and anatomical shapes for craniofacial applications. A complete offering is provided on our website www.su-por-ior.com.

SU-POR®



REFERENCES

Habiballah, JA, Bamousa . "Allographic and alloplastic auricular reconstruction. Saudi Med Journal (2000) 12, 1173-1177.

FDA 510(k) Substantial Equivalence Determination Letter Dated June 13, 2014

Habiballah, JA, Bamousa . "Allographic and alloplastic auricular reconstruction. Saudi Med Journal (2000) 12, 1173-1177.

<http://microtiaearsurgery.com/hearing-loss/timing-of-atresia-repair>

SU-POR Surgical Implants Instructions for Use



August 5, 2015

SU-POR®
BY PORIFEROUS®

REIMAGINING POROUS IMPLANTS

Enhanced flexibility

Distributed by:
SM Synergy Medical Corporation
(626) 254-9690 / Fax (626) 254-9691
www.synergymedcorp.com

Frequently Asked Questions

How are SU-POR Ear Implants different from MEDPOR Ear Implants?

While both implants are made from the same materials porous polyethylene (HDPE) and are used for the same type surgeries, SU-POR Ear Implants are manufactured using proprietary technology that, according to surgeon feedback, yields a higher quality result. The design and production team has over 70 years of combined experience working with porous polyethylene (HDPE) implants. This experience is more than any other porous polyethylene manufacturer in the world.

Why are SU-POR Ear Implants more flexible than MEDPOR Surgical Implants?

The key reasons that SU-POR Ear Implants are more flexible than MEDPOR Surgical Implants are the proprietary processes, the consistency with which the implants are made, and the key design elements. Based on the experience of members of the Poriferous team, formerly involved in the manufacture of MEDPOR, and feedback from surgeons who have used both SU-POR and MEDPOR implants, SU-POR is more flexible and less likely to break when manipulated.

How long have SU-POR Ear Implants been used?

The first SU-POR Ear Implantation was performed on February 27, 2015. To date there have been more than 20 ear reconstruction surgeries using the SU-POR Ear Implant. Ear implants made with porous polyethylene (HDPE) have been used successfully for more than 20 years.



Are SU-POR Ear Implants biocompatible?

Yes, SU-POR Ear Implants are biocompatible. Biocompatibility was confirmed through the required regulatory processes.

Can Canalplasty (Atresia repair) be used with SU-POR Ear Implants?

SU-POR Ear Implants may be used with Canalplasty. It is recommended by some surgeons that canalplasty be performed prior to ear reconstruction to avoid damage to the reconstructed ear, however, it can also be performed following ear reconstruction surgery.

What is the difference in the materials used to manufacture SU-POR Ear Implants and MEDPOR Ear Implants?

There is no difference between the materials used to manufacture SU-POR Ear Implants and MEDPOR Ear Implants. The material used is a high-density porous polyethylene (HDPE). Comparison testing was conducting during the regulatory clearance process to market SU-POR Surgical Implants.

What age can ear reconstruction be performed with SU-POR Surgical Implants?

Age appropriateness is determined by the surgeon. There are clinical papers that talk about ear reconstruction being performed at age three.

Have there been any reported issues with rejections, or complications with SU-POR Ear Implants?

To date there have been no reported complications or rejections using SU-POR Surgical Implants. There are various studies that report very low complication rates for porous polyethylene (HDPE) implants. One such retrospective study covering 15 years of use of porous polyethylene implants reported a 94% success rate.

Can my child get their ears pierced if they have a SU-POR Ear Implant?

In most cases, yes, consult your surgeon to discuss the timing and appropriateness of ear piercing of the reconstructed ear.

Can a SU-POR Ear Implant custom size, or is it one size fits all?

SU-POR Ear Implants can be custom-sized as the design is intended to be carved and shaped intraoperatively by the surgeon to provide a customized fit for the patient.

Distributed by:

 Synergy Medical Corporation

(626) 254-9690 / Fax (626) 254-9691

www.synergymedcorp.com