POLYTECH informed®

Information for reconstructive and aesthetic plastic surgeons

Issue 02/2015

Microthane® – Tradition and Innovation

A successful material in the hands of an expert company

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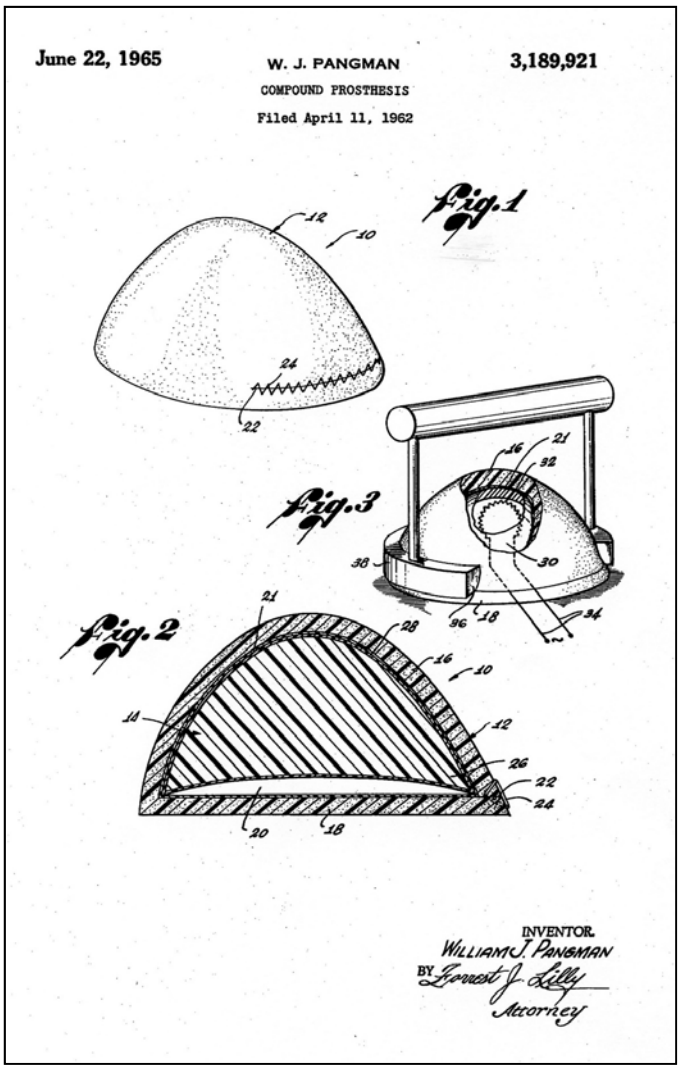
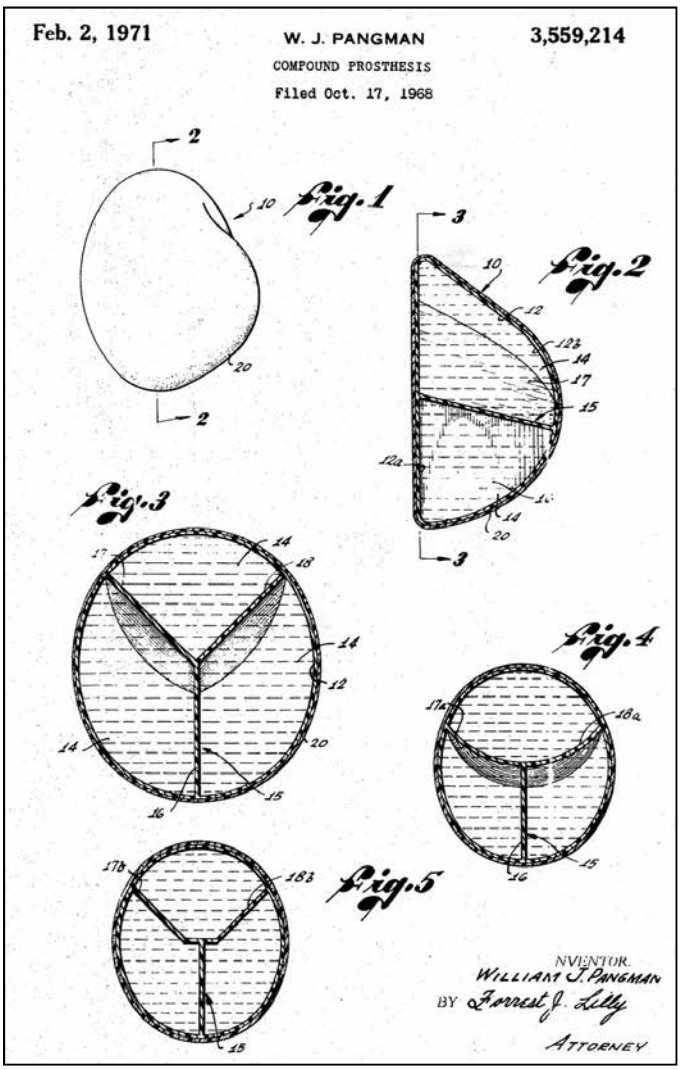
William J. Pangman, a genious inventor, had designed a silicone-gel filled implant long before Cronin and Gerow invented theirs in 1962: Pangman's first patent was submitted in 1954 and published on 15 July 1958.

On 11 April 1962, Pangman submitted for patenting an improved variation. It heat-sealed the polyurethane-foam edges around the implant. The corresponding patent was published on 22 June 1965. The technique was in use until the late 1990s.

Submitted on 4 June 1965 and published on 6 February 1968, he designed the first anatomical implant. At the time, cohesive gel was not yet available. Therefore, the implant had been equipped with a support that was formed like an Epsilon. This Y-support and the anatomical shape gave the implant series its name: Natural Y. The product itself was submitted for patenting on 17 October 1968 and the patent published on 2 February 1971. It was later called Optimam®. It is still in use today under the same name, filled with the state-of-the-art highly cross-linked gel.



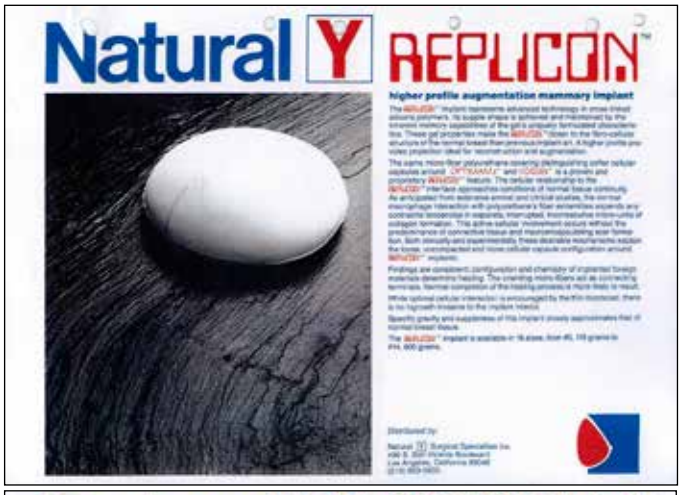
Pangman patent n°2



Pangman patent n°4

Pangman filed one of his last inventions, an adaptable implant, on 30 January 1970 and it was patented on 15 August 1972.

A very clever medical instruments designer named Hal Markham took Pangman's patent and developed the first Microthane® implants under the names of Mêmе®, Replicon®, and Optimam®. The production unit that manufactured these implants was called



Aesthetec, the marketing unit adopted the name Natural Y. These companies were represented worldwide by distributors.

In 1986, Cooper Surgical took over Aesthetec and Natural Y and continued distribution through the established channels, adding POLYTECH to their distributor network in that same year.

In 1989 then, Bristol Myer Squibb integrated the distribution into its business. The SBU – strategic business unit – Zimmer took over and the Brazilian distributor was discharged. POLYTECH, however, continued to market the Mêmе, Replicon, and Optimam implants not only in Germany but all over Europe.

In 1991/92, after the voluntary withdrawal of Bristol Myer Squibb from the breast-implant market, POLYTECH and the former Brazilian distributor decided to cooperate in manufacturing and distributing the polyurethane-covered implants. POLYTECH was to market in Europe, the Soviet Union and the states under the Warsaw Pact, the Brazilian company in the rest of the world.

In Europe, POLYTECH received the first approval to CE-mark their implants as early 1995. This was long before competitors were ready to apply for that certification which became mandatory at the end of the transition period in December 1998.

In 2008, the cooperation between POLYTECH and the Brazilian company was terminated. POLYTECH relocated the complete production to Germany and from then on marketed the implants globally.

Microthane®, Mêmе®, Replicon®, Optimam®, and Opticon® are registered trademarks of POLYTECH Health & Aesthetics.

Breast implants made by POLYTECH are quality implants manufactured in Germany.

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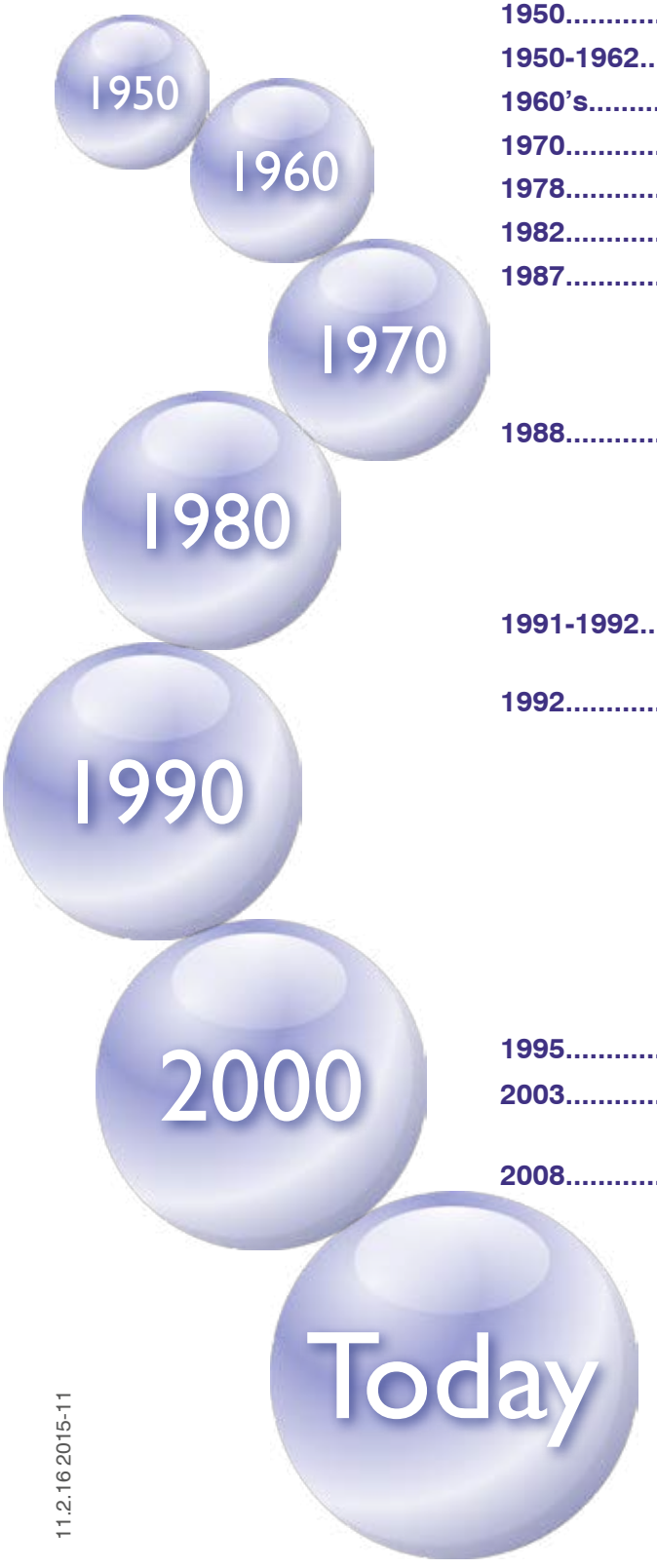

1950..... Ivalon® foam

1950-1962... Patent for Microthane® implants by John W. Pangman

1960's..... Hall Markham acquires Pangman's patent.

1970..... 1st publication on Microthane® by Frank Lloyd Ashley

1978..... Implants produced by Rudi Schulte (Heyer/Schulte)

1982..... Implants produced by Cox Uphoff

1987..... POLYTECH becomes the European distributor for AESTHETECH – Aesthetech being the manufacturer selling via Natural Y.

1st Polyurethane Workshop in Germany

1988..... Launch of the "implant passport" for Microthane® implants manufactured for POLYTECH/AESTHETECH

Bristol Meyers Squibb acquires all rights from Aesthetech and Natural Y and incorporates the implant business into their medical-devices unit Surgitek.

1991-1992... Bristol Meyers Squibb/Surgitek shuts down all activities, voluntarily, due to the legal situation in the USA.

1992..... POLYTECH acquires all available stock of Microthane® implants in order to satisfy the demand on the European market for the time being.

POLYTECH collaborates with surgeons in Germany to advance the development of Microthane® implants – shell production and filling at the time realized in Brazil.

Quality control, packaging and sterilization are executed by POLYTECH in Germany

Biocompatibility tests + TDA in-vitro release test

1995..... First company to receive CE mark approval for class IIb

2003..... First company to receive CE mark approval for breast implants, since then class III medical devices

2008..... Production of the Microthane® implants – Même®, Replicon®, Opticon®, Optimam® – exclusively in Germany and global expansion of sales activities of POLYTECH Health & Aesthetics

- ISO 13485
- ISO 9001
- MDD CE Annex II, Section 3
- MDD CE Annex II, Section 4
- ANVISA Inmetro
- KFDA

MADE IN GERMANY

11.2.16 2015-11

The success of a material in the hands of an expert company