Silicone in prosthetics – Properties and Use

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Agenda

• About Össur
• About Silicones
• Use of Silicones in prosthetics
ÖSSUR TODAY – WHO WE ARE

- Employees: ~ 2,500
- Sales: ~ > $ 500m
- Global leader in non-invasive orthopaedics
- Second largest player in bracing and supports and prosthetics worldwide
- Growing through innovation and expanding in the value chain
- Listed on Nasdaq OMX Copenhagen
OUR STRATEGY

VISION
LEADING COMPANY IN NON-INVASIVE ORTHOPAEDICS

MISSION
WE IMPROVE PEOPLE’S MOBILITY

GOAL
PROFITABLE MARKET SHARE GROWTH

MAIN FOCUS AREAS

INNOVATION
GROWTH
EFFICIENCY

VALUES
HONESTY – FRUGALITY – COURAGE
GROWTH STORY

Prosthetics consolidation
Prosthetics integration and restructuring
B&S consolidation
B&S integration and restructuring
Growth

CAGR: 25%

Sales
EBITDA
% margin

$ million


0 10 20 30 40 50 60 70 80 90 100 110 120 130 140 150 160 170 180 190 200 210 220 230 240 250 260 270 280 290 300 310 320 330 340 350 360 370 380 390 400 410 420 430 440 450 460 470 480 490 500 510 520 530 540 550 560 570 580 590 600

0% 10% 20% 30% 40% 50%
GLOBAL PROVIDER OF HEALTHCARE SOLUTIONS

USER PROFILE
- People recovering from fractures, ligament injuries or need a post operative treatment
- People living with osteoarthritis

IMPROVING PEOPLE’S MOBILITY
- Products stabilizing joints
- Non surgical treatment by unloading affected joint with braces
- Complete product offering for lower extremity prosthetics
- Advanced microprocessor controlled feet and knees

Bracing & supports
- Injury Solutions
- OA

Prosthetics
- Mechanical products
- Bionic products
<table>
<thead>
<tr>
<th>Sector</th>
<th>Market Dynamics</th>
<th>Market</th>
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| Bracing & supports | • Aging population  
                          • Prevalence of Osteoarthritis  
                          • Demand for quality of life  
                          • Reimbursement               | # 3 globally  
                          • Market size: $2,700m         
                          • Expected market growth: 3-4% |          |
| Prosthetics     | • Aging population  
                          • Technological developments  
                          • Vascular diseases & diabetes  
                          • Reimbursement               | # 2 globally  
                          • Market size: $950m           
                          • Expected market growth: 3%   |          |

1 Based on total sales split in 2014
GLOBAL OPERATIONS – WELL DIVERSIFIED

Operations in 18 countries - 2,500 employees
ÖSSUR WORLDWIDE IP PORTFOLIO
STATUS Q3 2015

• Registered patents: 1095
• Pending applications: 397
Silicone as biomaterial
Fact

Most of you have been in contact with silicone in some form today
History of silicone

• Before 1930: Silicone atom compounds with Si-C bonds created and investigated
• 1930-40: Silicone commercialized
• 1940’s-present: Silicone bio-inertness and properties investigated
• 1950’s: Silicone first used in medical applications
• 1980’s: Silicone liners first produced by Össur
Characteristics of silicones

- Non-reactive
- Thermally stable/ Non-combustible
- Electrically insulating
- Optical clarity
- High permeability to gases
- Radiation resistant
- High purity
Properties of silicone elastomers

• High elongation (typically 600 - 1000%)
• Good tear strength
• Unique modulus at typical elongation
• Controllable softness
• Low compression set
• Oxygen permeability
• Bio-inert
Typical uses of silicone

- Semiconductors (electronics)
- Automotive (gaskets and seals)
- Aerospace (seals)

- Implants
- Other medical grade products
- Additives in various cosmetic products
The Conversion

From sand to... silicone liner
Preparation of silicone

\[
\text{SiO}_2 + 2C \rightarrow \text{Si} + 2\text{CO}
\]
Quartz coke

\[
\text{Si} + 2\text{CH}_3\text{Cl} \rightarrow \text{Me}_2\text{SiCl}_2 + \{\text{other}}
\]

\[
2\text{Me}_2\text{SiCl}_2 + \text{H}_2\text{O} \rightarrow 2\text{Me}_2\text{Si(OH)}_2 + \text{HCl}
\]
Unstable
Preparation of silicone - cont.

\[
\text{HO[\((CH_3)_2SiO\)]_M}H \quad \xrightarrow{\text{KOH}} \quad \text{Linear siloxane}
\]

\[
\text{Octamethylcyclotetrasiloxane, D}_4
\]
Preparation of silicone - cont.

D4 + Endblockers → Linear polymer

Base or
Acid
catalyst

Linear polymer + various additives → Silicones with different properties
The silicone family tree

- **Silicone**
  - **Fluids (Free chains)**
    - Personal care products
  - **Gels (Crosslinked)**
    - Soft tissue implants
    - Wound and burn treatment
  - **Elastomers (Crosslinked and reinforced)**
    - Catheters
    - Prosthetic products
    - Intraocular lenses
  - **Resins (Heavily crosslinked)**
    - Pressure sensitive adhesives
    - Reinforcement for optically clear silicone
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    - Reinforcement for optically clear silicone
Grades of silicone elastomers

• Medical grade – Unrestricted
  - Suitable for long term implants (>28 days)
• Medical grade – Restricted
  - Suitable for implants up to 28 days
• Engineering grade
  - Same material as the medical grade but less testing on each batch, listed on FDA master list.
Silicone - Use in prosthetics
The task
The prosthesis

Liner

Socket

Foot
Matching needs and solutions

Clinical Need
- Suspension
- Comfort
- Fit
- Skin care

Technical Solution
- Elongation
- Compression set
- Durability
- Biocompatibility
Tensile Strength

• According to ASTM D412-06a
• To measure tensile properties of various silicones, namely Force @ 100% elongation [N/mm²], Force @ 200 % elongation [N/mm²], Strain @ Peak [%], and Stress @ Break [N/mm²]
Physical properties - Modulus

Stress-strain curve

Load (N) vs. Elongation (%)

-100 0 100 200 300 400 500 600

-20 0 20 40 60 80 100 120 140 160 180

Elongation (%)
Tear Strength Measurements

• According to ASTM D2240
• Tear strength is defined as the maximum force per mm² required to tear silicone which already has a nick in it
Durometer

- According to ASTM D 2240-05
- To compare the indentation hardness in silicone elastomers
The users
Silicone elastomer, Iceross

Dimethylsiloxane-chains + SkinCare ingredients =

Stiffness modified by chain length, level of crosslinking & skincare additives
Össur main silicone types

**ICEROSS® COMFORT**
- Recommended for low to moderate activity
- Perfect for users that require a comfortable liner with cushioning over sensitive areas
- SenSil Gel silicone cushions the limb
- Strong, durable nylon fabric cover

**ICEROSS DERMÖ®**
- Recommended for low to moderate activity
- Ideal for vascular patients and those with sensitive or bony limbs
- Made with DermoGel®, the softest Iceross silicone
- Active Skin Care soothes and maintains healthy skin
- Supplex® outer cover provides extreme wear and tear, strength, and durability
- Wave feature allows for easier knee flexion by easily stretching over the patella

**ICEROSS SYNERGY®**
- Recommended for moderate to high activity
- Also ideal for users with redundant tissue who need soft tissue stabilization
- Dual Durometer Silicone: the outer layer provides outstanding stability, while the soft, inner layer heals and protects against impact
- Active Skin Care soothes and maintains healthy skin, including menthol to control odor
- Wave feature allows for easier knee flexion by easily stretching over the patella
THE ANATOMY OF AN ICERoss LINER BY OSSUR. INSPIRED BY HUMAN PERFORMANCE.

IMPACT LEVELS

Use the figure below to determine which liner best matches the desired activity level.

LOW IMPACT LEVEL
Daily activities involving gentle strides, walking with the use of a walking aid, and example: Moving around at home, modest walking in the community.

MODERATE IMPACT LEVEL
Daily activities involving average walking, with the ability to vary speed or walking pattern. Example: Going to the shops, moderate outdoor walking.

HIGH IMPACT LEVEL
Daily activities requiring fast walking, jogging and climbing stairs. Example: Heavy lifting, manual labor, recreational sports.

EXTREME IMPACT LEVEL
Activities involving running, track and field, sprinting, and long-distance running. Example: Track and field sports.

LINER FEATURES

Use the following icons to help differentiate Ossur’s wide range of liner performance characteristics.

SEAL-FIT
Recuperated Knit fabric provides improved retention, comfort, and minimal wrinkling. Can be used with either locking or non-locking corsets.

LOCKING
The locking feature offers users first, secure, and comfortable a system. Can be used with either locking or non-locking corsets.

STABILIZING MATRIX
Unique integrated matrix allows radial stretch and limits vertical stretch for increased stability and skin comfort.

DUAL DENSITY
DUAL DENSITY
Two silicone densities work together: inner layer offers comfort and protection to the skin, outer layer offers shock absorption and stability.

FABRIC COVERAGE
The outer layer provides advanced wear and tear, strength, and durability while allowing radial stretch and comfortable activity.

ACTIVE SKIN CARE
Gelshield and keratin have been treated with Dermastay silicone to soothe and help maintain healthy skin.

CUSHION
A soft, extra thick about pad improves user comfort, protects sensitive distal ends, conforms to irregular distal shapes and features an external silicone cup for rotation control and impact protection.
Exposure

- We estimate that everyday Össur silicone liners cover 50 – 60000 m² of human flesh
- That is about the size of 7-8 average size football fields
- Use time per day can be 12-16 hours
Why silicone?

• Stability and Comfort
  - Good elastic properties ➔ reliable suspension
  - Conforms to residual limb shape ➔ total contact

• Biocompatibility
  - Long history in medical use ➔ very low risk of medical problems due to the material
  - Stable material ➔ very low allergy risk

• Durability
  - Smooth surface ➔ easy to clean and maintain
  - Good mechanical properties ➔ durable liners
The future

- More specialized solutions meeting individual needs (custom made solutions)
- Active ingredients – special functions
- Combination of materials
WE IMPROVE PEOPLE’S MOBILITY