

OssDsign

New clinical data strenghtens the case

- Updated clinical data from 1,055 cranioplasty procedures
- 8-11% infection risk with competing implant technologies
- Important data points to promote further uptake

Impressive updated post-market surveillance data

OssDsign announced updated post-market surveillance data for its lead product – the cranial implant OssDsign Cranial PSI for 1,055 procedures (previously 670 procedures). At a median follow up time of 21 months (range, 0-70 months) 44 implants (4.2%) have been explanted, i.e. surgically removed due to complications. Only 2.1% of the implants were explanted due to infections, which is a slight improvement from the previously reported 2.4%. Furthermore, since most postoperative infections occur within 1-3 months, the majority of all patients (median follow-up time 21m) should be safe from such explantations going forward. Roughly 77% of the OssDsign Cranial implants were ordered by University hospitals with a high-level trauma unit, usually a sign of a new and groundbreaking technology being implemented. Importantly, this constantly growing data set comes from 181 different hospitals across Europe, Asia and the US, showing that the outcomes are reproducible across different hospitals and countries.

2.1% explantations due to infections is best-in-class

As illustrated below, infection risk across competing materials for cranioplasty typically ranges between 8-11%. Hence, it is one of the most common reasons for implant removal. These complications represent a significant economic burden. For example, the cost for managing a case of infection can cost ~USD 100K in the US. This cost usually needs to be covered by the hospital's budget, as most infections occur within the first three months after surgery, a period in which the hospital does not receive reimbursement from the insurers for corrective surgery.

Important selling points for reimbursement and uptake

We believe this is an important data point in terms of improving reimbursement and clinical uptake as OssDsign continues to win new hospital accounts. The best-in-class clinical data should also provide a good foundation for its ongoing health economic data collection, as well as discussions with potential group purchasing organizations (GPOs) going forward.

Fast comment

Company-sponsored research: Not rated

Share price (SEK) 19/01/2021 15.0
Healthcare, Sweden
OSSD.ST/OSSD SS

MCap (SEKm) 331
MCap (EURm) 33
Net debt (EURm) -9

No. of shares (m) 22.2
Free float (%) 57
Av. daily volume (k) 21

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Updated post-market surveillance infection data compares well to other implant alternatives

Hospital type	Number of hospitals	Primary cause of explantation	Number of patients (%)
University Hospital	109	Infection (Early post-op)	22 (2.1)
General Hospital	63	Tumour Recurrence	3 (0.3)
Army Hospita	1	Persistent Wound Dehiscence	13 (1.2)
Veteran Hospital	1	Hematoma (Early post-op)	3 (0.3)
Private Hospital	7	Non-device Related Dura Rift	1 (0.1)
Total	181	ABF Resorption	1 (0.1)
		Aesthetic	1 (0.1)
		Total	1055

~8.9pp better than autologous bone
 Average infection risk for autologous bone transplants 11%
Kwarciniski et al. 2017; Corliss et al. 2016

~6-7pp better than alloplastic implants (PMMA)
 Infection risk for PMMA cranial implants ~7-11% (PEEK implants ~6% infection risk)
Kwarciniski et al. 2017; Punchak et al. 2017

~5-6pp better than titanium implants
 Infection risk for titanium cranial implants ~8%
Mikami et al. 2017

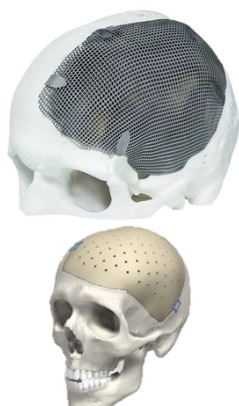
Source: ABG Sundal Collier, company data

Combining mechanical and biological features

Titanium/Alloplastic implant

Provides good mechanical stability ✓

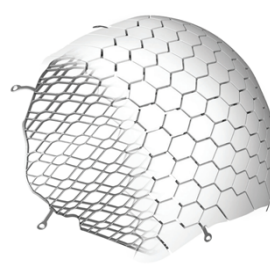
Poor integration and high rate of complications ✗



OssDsign's solution

Provides good mechanical stability ✓

Promotes bone growth and improved healing ✓

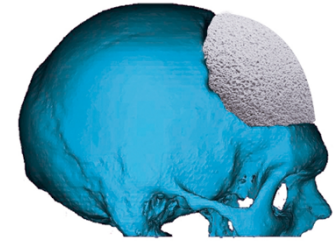


Implants based on a strong titanium structure covered by an outer shell made of the company's patented bioceramic material.

100% bioceramic implant

Promotes bone growth and improved healing ✓

Too fragile to protect the brain ✗



Source: ABG Sundal Collier, company data

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SEKm	2018	2019	2020e	2021e	2022e
Sales	13	17	27	61	124
<i>Sales growth (%)</i>	72.7	27.2	57.6	130.7	102.2
EBITDA	-47	-79	-74	-70	-47
<i>EBITDA margin (%)</i>	-350.7	-470.7	-278.5	-114.0	-37.7
EBIT adj	-50	-84	-81	-79	-57
<i>EBIT adj margin (%)</i>	-378.0	-495.0	-303.7	-127.9	-45.8
Pretax profit	-56	-84	-81	-79	-58
EPS rep	-11.00	-5.45	-3.67	-3.58	-2.61
<i>EPS growth (%)</i>	19.8	50.4	32.6	2.5	27.3
EPS adj	-10.73	-5.31	-3.52	-3.41	-2.40
DPS	0	0	0	0	0
EV/EBITDA (x)	na	-2.0	-3.2	-1.3	-3.6
EV/EBIT adj (x)	na	-1.9	-3.0	-1.2	-3.0
P/E (x)	na	-3.2	-4.1	-4.2	-5.7
P/E adj (x)	na	-3.2	-4.2	-4.4	-6.2
EV/sales (x)	na	9.3	9.0	1.5	1.4
<i>FCF yield (%)</i>	na	-32.7	-26.1	-28.2	-24.5
<i>Dividend yield (%)</i>	na	0	0	0	0
Net IB debt/EBITDA	0.2	1.4	1.2	3.4	3.5
<i>Lease adj. FCF yld (%)</i>	na	-32.9	-26.2	-28.6	-25.1
Lease adj. ND/EBITDA	0.2	1.4	1.3	3.4	3.4

Analyst certification

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