South Australian Policy Advisory Committee on Technology (SAPACT)

Health Technology Assessment (HTA) Decision Summary

Government of South Australia

SA Health

Motiva® breast implants for breast reconstruction surgery

SAPACT MEETING DATES	19th SAPACT Meeting, 13 September 2019
APPLICATION #	1929
TECHNOLOGY	Motiva® SilkSurface™ PLUS Qid™ (ARTG 282776) and Motiva® Ergonomix® Round SilkSurface with Qid breast implants (ARTG 282777) By Establishment Labs, Costa Rica
TECHNOLOGY CLASSIFICATION	TGA class III high-risk
PATIENT INDICATION (TGA)	TGA intended purpose The TGA intended purpose of the Motiva breast implants are: • Breast augmentation for women of at least 18 years of age, including previous augmentation to increase the breast size and revision surgery to correct or improve the result of a previous breast augmentation surgery. • Breast reconstruction, including previous reconstruction to replace breast tissue that has been removed due to cancer or trauma, or that has failed to develop properly due to a severe breast anomaly, as well as revision surgery to correct or improve the results of a previous breast reconstruction surgery.

SAPACT DECISION

☒ Restricted recommendation for clinical use. Clinicians are required to obtain informed patient consent and to report clinical and device outcomes to the Australian Breast Implant Registry (ABIR) and/or TGA for monitoring purposes.

SAPACT Evidence Review Conclusions

There were no published peer-reviewed papers that focused on Motiva breast implants outcomes in breast reconstruction, only on breast augmentation. Results from the three observational uncontrolled studies (NHMRC level IV evidence) found that Motiva breast implants for breast augmentation were generally safe with low complications and good satisfaction rates. However, there was a high ptosis rate of 53.1% and a nominal 0.89% increase in self-esteem/quality of life scores compared to 6 years post-implantation. No published economic evaluation was found for the Motiva breast implants. Motiva breast implants are priced similar to existing comparators. In terms of advanced surgical training, surgeons were advised to exercise mandatory caution when manipulating the inframammary fold and be aware that the Motiva implants exhibit different behavioural properties compared to macro-textured and polyurethane-coated implants for pocket preparation. High quality controlled trials with long-term data are required to inform the safety, clinical and cost-effectiveness of this technology.

TGA Review (September 2019 Results)

The TGA review on breast implants and their potential association with anaplastic large cell lymphoma (BIA-ALCL) had resulted in the removal of some textured breast implants from the Australian market with effect from September 2019. Textured and smooth breast implants which are still listed on the TGA Australian Register of Therapeutic Goods (ARTG) are now subjected to stricter clinical outcomes and device performance monitoring to the TGA and to the ABIR.

SAPACT Advisory Recommendations

SAPACT recognised the context and evidence challenges for the smooth Motiva breast implants with RFID chip compared to textured breast implants. Although the level and quality of scientific evidence is low, at this time the smooth Motiva breast implants have demonstrated reasonable evidence of safety compared to textured breast implants and are equivalent in pricing. Therefore, SAPACT recommends the restricted approval of the use of SilkSurface™ PLUS Qid™' (ARTG 282776) and 'Ergonomix® Round SilkSurface with Qid' (ARTG 282777) in 20 treatments per year at the TQEH, subjected to (1) informed patient consent on the risks and benefits of the Motiva implants compared to other smooth or textured silicone breast implants and (2) clinicians reporting of clinical and device outcomes to the ABIR and/or TGA for monitoring. Clinicians are to provide copies of the outcome reports annually to SAPACT for noting.

REGULATORY APPROVALS

☒ **ARTG**: 22/11/2016 Ergonomix Round SilkSurface with Qid (ARTG 282777); SilkSurface PLUS Qid (ARTG 282776); SilkSurface PLUS (ARTG 282778); Motiva sizers (ARTG 280546)	☐ **US FDA**: Nil, pending results from a US FDA IDE single arm, multi-centre 10-year trial (NCT03579901; April 2018 – March 2028)	☒ **EU CE mark**: 24/05/2017 In Europe, only the Motiva VelvetSurface PLUS and VelvetSurface PLUS Qid are approved for use, which are not available in Australia.

QUALITY OF EVIDENCE A SAPACT Evidence Review was developed to inform SAPACT's decision-making.

Quality of Evidence	Comprehensive systematic searches were conducted in 9 published scientific databases and 25 grey literature sources. Since there was no paper focused on Motiva breast implants outcomes in breast reconstruction, the inclusion criteria were expanded to include papers on Motiva breast implants in breast augmentation. There were no published peer-reviewed papers that focused on Motiva breast implants outcomes in breast reconstruction. No HTA reports or systematic reviews on Motiva breast implants were found. Through a comprehensive systematic literature search in 34 published and grey literature sources, three observational uncontrolled studies (NHMRC level IV evidence) on breast augmentation were found and included in the review. In terms of conflicts of interest, Quiros 2019 is an industry-funded paper, and Sforza 2017 is a co-funded industry supplement. Huemer 2018 is the only paper of which the authors declared no conflicts of interest and they do not have any financial interest in Motiva breast implants. All cases were carried out by the first author in Huemer 2018.

CLINICAL NEED

Burden of Illness	Burden of illness resulting in breast reconstruction is unclear from the literature. According to the TGA, between 13,000 - 17,000 breast implant procedures are performed in Australia each year. The ABIR had captured 6,990 Motiva breast implants (Ergonomix® Round and SilkSurface™ Plus) inserted in Australia over three years, from February 2016 to February 2019.

Need	Silicone breast implants are used in breast reconstruction and breast augmentation surgeries. Since the 1980s, silicone breast implants had raised serious safety concerns in patients due to non-medical grade silicone resulting in higher and earlier rates of implant ruptures and improperly sterilised breast implants leading to infections. Internationally, recent concerns are focused on textured breast implants and BIA-ALCL. In July 2019, following a review, the TGA proposed banning some textured breast implants and suspending several others. The Motiva breast implants are smooth surface, are at low risk of BIA-ALCL and are the only breast implants on the market with a RFID chip and a mobile app, allowing the identification of the implant during a recall without undergoing surgery.
CLINICAL BENEFIT	
Safety	Results from the three observational uncontrolled studies found that Motiva breast implants for breast augmentation were generally safe with low overall complication rates (7%; 0.36% and 0% across the studies). Other safety outcomes measured included revision rates; implant dislocation and mobility; implant rupture; implant exchange/replacement; postoperative haematoma; reoperation; seroma; wound dehiscence; infection; changes in nipple sensitivity and twinges. The studies reported no cases of capsular contracture (Baker Grade III/IV), rippling, double capsule, ALCL, inadequate scarring, pruritus, reported loss of volume, symmastia, persistent swelling, breast pain, redness/rash, allergy and life-threatening events. Deaths were not specifically reported from any of the studies. Till date, the TGA Database of Adverse Event Notifications (DAEN) for Medical Devices has not documented any adverse events for Motiva breast implants.
Effectiveness	There was a high ptosis rate of 53.1% in one study. Two of three studies found full or high satisfaction rates by the patients and surgeons. Quality of life and self-esteem scores generally increased after breast augmentation. Overall, a nominal 0.89% increase in self-esteem/QoL scores was observed compared to 6 years post-implantation.
SUITABILITY OF PATIENT GROUP	
Suitability of Patient Group	The Motiva breast implants will be considered for patients undergoing breast reconstruction surgery. A systematic search through the published literature found no international guidelines or specific evidence on the patient group who may benefit most from the Motiva breast implants. There are also no published recommendations, reports or consensus regarding the optimal patient selection for smooth versus textured breast implants.
FINANCIAL CONSIDERATION	
Device costs	In SA Health, Motiva breast implants are priced similar to existing comparators.
Value for Money	No published economic evaluation was found for the Motiva breast implants. The specific Motiva implants will replace the existing higher textured surface breast implants in breast reconstruction surgery which are known to have a higher risk of BIA-ALCL.
Australian Funding Approvals	Interstate technology committees were contacted and no formal assessment for the Motiva breast implants had been undertaken. The Motiva breast implants are listed on the Commonwealth Prostheses List with the approval of Prostheses List Advisory Committee (PLAC). No other local or international HTA and government agencies have evaluated the Motiva breast implants for the purposes of public funding, reimbursement, policy or consideration for uptake in routine clinical practice.
FEASIBILITY OF ADOPTION	
Organizational Feasibility	To be managed appropriately by the plastic surgeons at TQEH with relevant management approvals. The applicant noted that the data will be collected prospectively by the ABIR and TQEH Breast Reconstruction Database. Patient outcomes will be audited every quarter.
Credentialing and Competency	In terms of advanced surgical training, surgeons were advised to exercise mandatory caution when manipulating the inframammary fold and be aware that the Motiva implants exhibit different behavioural properties compared to macro-textured and polyurethane-coated implants for pocket preparation. The Australian version of the Directions for Use (DFU) for the Motiva breast implants stated that only surgeons with qualified training and certified by the corresponding national medical board should use this product. The applicant indicated that there is no ancillary training for the insertion of Motiva breast implants once a surgeon is familiar with the prosthesis differences compared to previous iterations. A similar procedure may be used. Any education required will be provided by the supplier at no additional cost. Since there is 90% usage of textured breast implants in Australia, surgeons may have a vacuum of experience related to smooth breast implants.3 SAPACT viewed that the approved clinician(s) should be appropriately trained, credentialed (if required) and endorsed by the SA Health Credentialing and Scope of Practice Committee to implant the Motiva breast implants (refer to paragraph 3.4.3 New Clinical Procedures, Technologies and Treatments of the SA Health Credentialing Policy Directive).
CONSISTENCY WITH EXPECTED SOCIETAL/ ETHICAL/ LEGAL VALUES	
Values	Consistent with expected societal, ethical and legal values at this time.
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