RAPID HTA REPORT		
N° della richiesta	**Data della richiesta**	**Richiedente**
293	20/04/2023	AOUP - Senologia

Tipo di report	
Nuovo report	Sì
Aggiornamento di un report precedente	No
Se aggiornamento, indicare il motivo:	

Dati generali della tecnologia			
Nome commerciale			
Protesi Mammarie sterili in silicone Motiva Implants® Ergonomix® Round SmoothSilk®/SilkSurface®			
Nome generico			
Protesi mammaria in silicone ergonomica			
Nome fabbricante			
ESTABLISHMENT LABS			
Nome fornitore			
MOTIVA ITALY SRL			
RDM	**REF**		
13129XX,1313XXX, 1322XXX, 1324XXX, 1832XXX.	-		
Tipo	**Marchio CE (data)**	**Classe di rischio**	**Approvazione FDA**
1	745219 R000 (24/05/2017)	Classe III	No
CND			
P060199 (Protesi mammarie altre)			
Problema clinico e razionale della richiesta			
La ricostruzione del seno e l'aumento del seno sono le principali ragioni per cui le donne si sottopongono a chirurgia plastica. Secondo la Società Americana per la Chirurgia Plastica Estetica (ASAPS), sono state effettuate più di 100.000 procedure di ricostruzione e circa 200.000 interventi di aumento del seno in USA nel 2020 [1]. Tali procedure prevedono l'impianto di protesi mammarie in silicone, la sicurezza delle quali è spesso stata oggetto di discussione. È stata scoperta un'associazione tra il linfoma anaplastico a grandi cellule (ALCL) e le protesi mammarie. Tuttavia, questa correlazione sembra essere più evidente in alcuni tipi di dispositivi, in particolare in quelli con superficie macro-strutturata piuttosto che in quelli con superficie liscia/nanostrutturata. La minore incidenza di ALCL in impianti con superficie liscia/nanostruttura potrebbe essere legata alla minore risposta infiammatoria, che comporterebbe anche una riduzione del rischio di contrattura capsulare, al momento però dimostrato in vitro [2-12].			
Indicazioni d'uso			
Le protesi mammarie sterili al silicone Motiva Implant di Establishment Labs sono indicate per le seguenti procedure in pazienti di sesso femminile: - Ricostruzione mammaria, compresa ricostruzione precedente per sostituire tessuti mammari rimossi a causa di un tumore o un trauma, o il cui sviluppo è stato compromesso per anomalie mammarie, così come la chirurgia di revisione volta a correggere o migliorare i risultati di un precedente intervento di chirurgia ricostruttiva. - Aumento mammario per donne di almeno 18 anni, inclusi precedenti aumenti per accrescere il volume del seno, e chirurgia di revisione per correggere o migliorare il risultato di un precedente intervento additivo.			
Paziente target			
Pazienti di sesso femminile che necessitano di ricostruzione mammaria; pazienti candidate a mastectomia monolaterale con particolare conformazione delle mammelle (volume medio-grande, ptosi medio-elevata); pazienti di sesso femminile di età > 18 anni che necessitano di mastoplastica additiva.			

Dati generali della tecnologia

Principali competitor

Attualmente in uso dal richiedente sono le protesi mammarie testurizzate Siltex in gel di silicone.

Dettagli tecnologici

Descrizione

La famiglia Motiva Implants Ergonomix Round SmoothSilk/SilkSurface consiste in dispositivi costruiti con strati successivi reticolati di elastomero di silicone e un involucro a bassa barriera di diffusione con BluSeal Technology, che insieme forniscono le caratteristiche meccaniche e l'integrità del dispositivo. La superficie dell'involucro, SmoothSilk/SilkSurface, è classificata come superficie liscia. Tali protesi mammarie sono composte da un involucro rotondo a lume singolo, un sistema di patch e un gel riempitivo in silicone (ProgressiveGel Ultima). Un microtransponder per l'identificazione a radiofrequenza (RFID) inserito nel gel è opzionale e disponibile per tutti i modelli di protesi. Questo microtransponder fornisce a ogni dispositivo un numero di serie elettronico unico per la tracciabilità, che può essere utilizzato per accedere a un database contenente le informazioni della protesi mammaria. Gli impianti sono disponibili in una vasta gamma di larghezze di base, proiezioni (profili) e volumi.

Elementi di innovazione

Motiva Ergonomix mostra una bassa risposta infiammatoria ed un grado di biocompatibilità superiore ad altri concorrenti, dovuti alla particolare ed unica topografia della superficie. Tale superficie è considerata, in base alla direttiva UNI EN ISO 140607_2018, inerente la classificazione delle superfici delle protesi mammarie, una superficie liscia (0 -> 10 mc) seppur non completamente (3,09 micron). Tale superficie potrebbe determinare una minore incidenza di ALCL, ma gli studi a supporto di questa ipotesi sono, ad oggi, studi in vitro.
Un altro elemento potenzialmente importante è rappresentato dal fatto che nei casi di mastectomia monolaterale su mammelle a volume medio-grande o ptosi medio-elevata le caratteristiche del gel Progressive Ultima potrebbero determinare una simmetria di forma e posizione con la mammella superstite senza intervenire sulla stessa con mastoplastica riduttiva o mastopessi, permettendo così la riduzione dell'invasività e dei tempi di sala operatoria. Purtroppo però non ci sono dati citabili riguardo al fatto che le protesi Motiva Ergonomix consentono di non eseguire la simmetrizzazione controlaterale.

Evidenze cliniche ed economiche

Studi clinici

A seguito di ricerca Pubmed con parola chiave "Motiva SilkSurface" sono stati rilevati 21 articoli, di cui 7 sono stati ritenuti pertinenti [8-9,11-15]. Di questi 7 studi, 1 [9] riguarda l'impiego di questa protesi in pazienti sottoposte a ricostruzione mammaria per tumore, mentre 6 riguardano l'impiego di questa protesi per l'aumento del seno per motivi estetici [8,11-15].

A single surgeon's experience with Motiva Ergonomix round SilkSurface silicone implants in breast reconstruction over a 5-year period [9]
Poiché sono poche le evidenze relative all'utilizzo di tale impianto nella ricostruzione mammaria, si riporta l'esperienza di un singolo centro.
E' stata condotta una revisione retrospettiva delle cartelle di pazienti sottoposte a procedure di ricostruzione mammaria primaria o di revisione, utilizzando Motiva Ergonomix, da Gennaio 2017 a Gennaio 2022. Sono stati estratti i dati demografici, chirurgici e sono stati completati i questionari BREAST-Q.
E' stato recuperato un totale di 156 pazienti consecutivi (269 seni). 257 sono state ricostruzioni *direct to implant* e 12 *expander to implant*. La contrazione capsulare è stata riscontrata in 4 seni (1.49%), increspature sono state osservate in 11 seni (4.08%), ischemia cutanea in 17 (6.31%), ematoma in 4 (1.49%) e sieroma in 6 (2.23%). La soddisfazione per l'impianto è stata 6.52 su 8.

A Single Center's Clinical Experience With Ergonomix Breast Implants [8]
Il presente studio retrospettivo riporta le prime esperienze di un centro chirurgico con protesi mammarie Motiva

Evidenze cliniche ed economiche

Ergonomix SilkSurface. Un totale di 356 pazienti (712 impianti) ha ricevuto impianto di Ergonomix SilkSurface tra Aprile 2014 e Ottobre 2018 da 3 diversi chirurghi e il follow-up minimo è stato di 12 mesi.
Sono state osservate solo 6 complicanze maggiori: una ptosi a 12 mesi (0.14%) e 2 contratture capsulari (0.28%), una a 14 mesi e una a 2 anni. Il 98% dei pazienti era estremamente o molto soddisfatto del risultato estetico ottenuto e i chirurghi hanno ritenuto che ci sia stato un miglioramento molto importante o importante nel 96% dei casi.

Six-Year Evaluation of Motiva Round and Ergonomix SmoothSilk Surface Silicone Breast Implants: A Two-Center, Two-Surgeon Outcome Analysis of 1053 Primary and Secondary Breast Augmentations and Augmentation Mastopexy [11]
I dati di 1053 mastoplastiche additive primarie e secondarie (2016 seni) effettuate tra Aprile 2015 e Dicembre 2020 in 2 centri sono stati valutati retrospettivamente.
Il tasso complessivo di complicanze a 6 anni è stato 4.9% (52 casi). La complicanza prevalente è stata lo spostamento inferiore dell'impianto al di sotto della piega sottomammaria originale nel 1.6% (17 casi). Doppia proiezione, simmastia o rottura dell'impianto si è riscontrato nello 0.2% (2 pazienti). I tassi di contrattura capsulare sono stati bassi, 0.4% (4 casi) in 6 anni. Nello 0.4% (4 casi) i pazienti hanno avvertito dolore. Non si sono verificati casi di reintervento o infezione.

Six-Year Prospective Outcomes of Primary Breast Augmentation With Nano Surface Implants [12]
L'obiettivo dello studio è stato quello di valutare in modo prospettico la sicurezza e l'efficacia degli impianti SmoothSilk/SilkSurface Motiva (famiglia di protesi di seno in silicone) nel follow up a lungo termine.
I chirurghi di un singolo centro di chirurgia plastica hanno intrapreso uno studio di follow-up di 10 anni sugli impianti. SmoothSilk/SilkSurface Motiva in donne sottoposte a mastoplastica additiva primaria. Il presente paper riporta i risultati a 6 anni. Un totale di 35 pazienti ha subito impianto tra Settembre e Dicembre 2010 e il 71.9% degli impianti sono stati posizionati per via sottomuscolare mediante incisione sottomammaria. Durante il follow-up di 6 anni, non si sono verificati casi di contrattura capsulare, rottura, doppie capsule o sieroma tardivo. La MRI non ha evidenziato complicanze correlate all'impianto. Sono stati eseguiti tre interventi di revisione per ragioni estetiche. Non sono state effettuate sostituzioni di impianti per ragioni mediche. Il livello di soddisfazione sia per i medici che per i pazienti è stato elevato in tutte le visite di follow-up. I punteggi sulla qualità della vita delle pazienti hanno subito incremento in seguito all'aumento del seno in media dello 0.89% a 72 mesi.

Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations [13]
Attraverso il presente studio è stata condotta una valutazione retrospettiva su 100 pazienti sottoposte a intervento primario di mastoplastica additiva, in 3 anni. Le pazienti sono state controllate per un minimo di 6 mesi dopo l'intervento. Inoltre è stata effettuata un'intervista sull'esito dell'intervento.
I motivi dell'intervento chirurgico sono stati ipoplasia (52%) e ptosi (28%). Tutti gli impianti sono stati posizionati attraverso un approccio sottomammario in una tasca sottomuscolare con volume medio dell'impianto di 370 cc con proiezione quasi completa (65%). Il tasso di revisione è stato del 7%. Sono stati osservati 4 casi di malposizionamento dell'impianto, una rottura dell'impianto, uno scambio dell'impianto per ragioni estetiche e una evacuazione dell'ematoma. Nonostante ciò, è stato raggiunto un tasso di soddisfazione del 100% per quanto riguarda l'esito post-operatorio sia per il paziente che per il chirurgo.

Preliminary 3-Year Evaluation of Experience With SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Center Experience With 5813 Consecutive Breast Augmentation Cases [14]
Il presente studio retrospettivo ha valutato la sicurezza degli Impianti Motiva in 5813 casi consecutivi di aumento del seno. Sono state valutate due diverse superfici testurizzate: SilkSurface (nanostrutturata) e VelvetSurface (microstrutturata). Gli impianti sono stati inseriti tra Aprile 2013 e Aprile 2016. Sono state segnalate 44 complicanze totali, con un tasso di complicanze complessivo di 0.76%. Il tasso di reintervento è stato 0.76% in 3 anni. Non si sono verificate complicanze tardive né casi di contrattura capsulare primaria. Non sono state osservate differenze nelle

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complicanze a causa della data dell'impianto. Tuttavia, tra i pazienti che hanno ricevuto impianti con volumi da 300 a 499 cc, i tassi di complicanze erano significativamente inferiori con gli impianti SilkSurface rispetto a VelvetSurface.

A Preliminary Retrospective Study to Assess the Short-Term Safety of Traditional Smooth or Microtextured Silicone Gel-Filled Breast Implants in Korea

[15]

Si tratta di uno studio retrospettivo preliminare per valutare la sicurezza a breve termine delle protesi mammarie in gel di silicone disponibili in commercio, impiantate in donne coreane.

Lo studio osservazionale e retrospettivo è stato condotto su un totale di 2612 pazienti sottoposte a mastoplastica additiva tra Gennaio 2017 e Agosto 2021. Nel complesso si sono verificati 248 casi (9.49%) di complicanze postoperatorie: 112 di sieroma precoce, 52 di deformazione, 32 di contrazione capsulare, 12 di ematoma precoce, 12 di rottura, 12 di infezione, 12 di deformazione da stiramento con eccesso di pelle e 4 di increspature. Complessivamente la sopravvivenza libera da complicazioni della protesi mammaria è stata stimata in 1.564,32 ± 75,52 giorni (IC al 95% 1416,39-1712,32). Motiva Ergonomix SilkSurface (superficie nanostrutturata) ha mostrato la sopravvivenza maggiore (1528,00±157,92 giorni [IC al 95% 1218,48-1837,56]) seguito da BellaGel SmoothFine (1458,4±65,76 giorni [IC al 95% 1329,56-1587,28]), Sebbin Sublimity (1322,00 ± 51,20 giorni [IC 95% 1221,64–1422,32]), BellaGel Smooth (1.138,72 ± 161,28 giorni [95% CI 822,6–1.454,84), il Mentor MemoryGel Xtra (superficie liscia) (698,4 ± 52,64 giorni [95% CI 595,28–801,52]) e Natrelle INSPIRA (380,00 ± 170,88 giorni [IC 95% 45,04–714,96]) in ordine decrescente. Considerando dei sottogruppi, sia Motiva Ergonomix che Mentor MemoryGel Xtra non hanno mostrato complicanze postoperatorie. Tuttavia BellaGel SmoothFine, Sebbin Sublimity e BellaGel Smooth hanno mostrato incidenze dell'8,87%, 4,84% e 1,61%, rispettivamente. Un'analisi dei sottogruppi ha mostrato anche differenze nell'incidenza delle complicazioni postoperatorie tra protesi mammarie microstrutturate e lisce (15,18% contro 16,67%).

Sperimentazioni cliniche in corso

Dalla ricerca sul sito clinicaltrials.gov con la parola chiave "Motiva Ergonomix" è stato rilevato un solo studio:

Studio NCT05449587: multicentrico, osservazionale, a singolo braccio con un minimo di 160 pazienti sottoposti a intervento chirurgico di protesi mammaria, da 3 a 10 anni dopo l'intervento. Gli outcome sono il tasso di rottura silente dell'impianto e soddisfazione e qualità della vita delle pazienti. Lo studio è in fase di arruolamento e il termine dello studio è programmato per dicembre 2023.

Linee guida

Nessuna Linea Guida

Analisi di costo-efficacia

Nessuna analisi di costo-efficacia

Report HTA

E' disponibile il seguente report australiano: South Australian Policy Advisory Committee on Technology (SAPACT): Health Technology Assessment (HTA) Motiva® breast implants for breast reconstruction surgery [16]. Tale report esprime una raccomandazione limitata per l'uso clinico. In particolare, i medici sono tenuti a ottenere il consenso informato del paziente e a riferire i risultati clinici del dispositivo all'Australian Breast Implant Registry (ABIR) e/o al TGA a scopo di monitoraggio. Il report evidenzia che non sono stati pubblicati lavori peer-reviewed incentrati sugli esiti delle protesi mammarie Motiva nella ricostruzione del seno, ma solo sull'aumento del seno; sono pertanto necessari studi controllati di alta qualità con dati a lungo termine per valutare la sicurezza, la clinica e il rapporto costo-efficacia di questa tecnologia.

Benefici attesi

Il potenziale beneficio derivante dall'impiego delle protesi con topografia SilkSurface, caratterizzate come protesi con superficie liscia, è rappresentato da una ridotta risposta infiammatoria e conseguente minore incidenza di contrazione capsulare e di ALCL, ma tale tesi è supportata solo da studi in vitro sulla superficie in esame.

Un altro potenziale beneficio è nei casi di mastectomia monolaterale su mammelle a volume medio-grande o ptosi

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medio-elevata dove le caratteristiche del gel Progressive Ultima potrebbero permettere una simmetria di forma e posizione con la mammella superstite senza intervenire sulla stessa con mastoplastica riduttiva o mastopessi. Tuttavia, non ci sono dati citabili riguardo al fatto che le protesi Motiva Ergonomix consentono di non eseguire la simmetrizzazione controlaterale.

Prezzo e costo terapia per paziente

Prodotto (Fabbricante)	Prezzo unitario (euro)	Costo terapia per paziente (euro)	Fabbisogno annuale (N. pezzi)
Motiva Implants Ergonomix® (ESTABLISHMENT LABS)	600-650	600-1.300	80 (suddivisi come segue: 35 per la AOUP, 35 per la AOUS, 10 per la AVNO)

Prezzo e costo terapia per paziente con le alternative terapeutiche già in uso

Prodotto (Fabbricante)	Prezzo unitario (euro)	Costo terapia per paziente (euro)
Protesi mammarie rotonde lisce in gel silicone	315	da 315 a 630

Impatto economico ed organizzativo
L'eventuale impiego di Motiva Ergonomix comporta un aumento della spesa visto che ha un prezzo superiore (il doppio) a quello delle protesi comparator.

Informazioni di rimborsabilità

Diagnosi principale (codice ICD9-CM)	Intervento (Codice ICD9-CM)	Codice DRG	Tariffa (euro)
174.X, 233.0; V52.4; 996.54	85.33/85.35; 85.53/85.54; 85.93	258; 461	3.044 (258); 2.613 (461)

Valutazione di innovatività (secondo Delibera regionale N° 737/2022, link e N° 1244/2022 link)

Dispositivo innovativo (S/N)	No
Se sì, indicare quali Criteri 1, 2 e 3 risultano soddisfatti:	

Dati riassuntivi

Numero della richiesta	Data della richiesta	Richiedente
293	24/04/2023	AOUP – Senologia e AOUS

Tecnologia

Motiva Implants® Ergonomix® Round SmoothSilk®/SilkSurface®

Conclusioni

La protesi Motiva Implants Ergonomix Round SmoothSilk/SilkSurface è formata da strati successivi reticolati di elastomero di silicone e un involucro a bassa barriera di diffusione con BluSeal Technology, che insieme forniscono le caratteristiche meccaniche e l'integrità del dispositivo. Tali protesi mammarie sono composte da un involucro rotondo a lume singolo, un sistema di patch e un gel riempitivo in silicone (Progressive Gel Ultima). La superficie dell'involucro, SmoothSilk/SilkSurface, è classificata come superficie liscia.

Fra i vari studi analizzati solo quello di Kaplan et al. 2023 [9] valuta l'impiego di questa protesi per la ricostruzione

del seno in pazienti con tumore alla mammella, gli altri studi valutano l'uso di Motiva Ergonomix per motivi estetici [8,10-15]. Riguardo alle limitazioni che emergono da queste evidenze, il principale problema è la totale assenza di confronti con altre protesi in termini di efficacia e/o sicurezza. L'unica parziale eccezione è lo studio di Sforza et al. [14] nel quale, confrontando la protesi Ergonomix con la protesi VelvetSurface, se da un lato non sono state osservate differenze nell'incidenza di complicanze nella popolazione complessiva, nel sottogruppo di pazienti che ha ricevuto impianti di volume compreso tra 300 e 499 ml, la protesi Ergonomix ha mostrato un'incidenza significativamente minore di complicanze; il valore significativo della p è tuttavia presunto non essendo riportato esplicitamente.

I potenziali benefici derivanti dall'impiego delle protesi con topografia SilkSurface sono due: 1) ridotta risposta infiammatoria e conseguente minore incidenza di contrazione capsulare e di ALCL; 2) nei casi di mastectomia monolaterale su mammelle a volume medio-grande o ptosi medio-elevata le caratteristiche del gel Progressive Ultima potrebbero permettere una simmetria di forma e posizione con la mammella superstite senza intervenire sulla stessa con mastoplastica riduttiva o mastopessi. Purtroppo questi benefici non sono ancora sufficientemente documentati; infatti ad oggi riguardo alla minore incidenza di ALCL sono disponibili solo studi in vitro, mentre sulla possibilità di non eseguire la simmetrizzazione controlaterale non c'è alcun tipo di trial. D'altro lato, il prezzo di Motiva Ergonomix è il doppio del prezzo delle protesi mammarie standard.

In conclusione, il CO esprime parere favorevole a condizione di una riduzione del prezzo di Motiva Ergonomix. In particolare, ritenendo di voler esprimere un'apertura all'innovazione potenziale, si accetta un prezzo non superiore al 15% del prezzo del comparator.

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APPENDICE 1

Vengono riportati per intero gli abstract delle Referenze da [8] a [15].

Referenza [8]

Background: This retrospective study reports on the early experience of a private surgical center with Motiva Ergonomix SilkSurface breast implants.

Objectives: The aim of this study was to examine the incidence of complications and satisfaction levels in women who received primary and revision breast augmentation or augmentation-mastopexy with Ergonomix SilkSurface breast implants.

Methods: A total of **356 consecutive patients** received Ergonomix SilkSurface breast implants between April 2014 and October 2018 by 3 different surgeons and were **followed-up for a minimum of 12 months**. Complications were assessed by measuring the rate of rupture, capsular contracture, malposition, late seroma, double capsule, reoperation, symmastia, ptosis, extrusion, and infection. Satisfaction with aesthetic results was assessed on a Likert scale by both surgeon and patient.

Results: Only 6 major complications were observed in these 356 patients (712 implants): 1 unilateral implant ptosis ("bottoming out") at 12 months (0.14%) and 2 capsular contractures (0.28%), 1 at 14 months and 1 at 2 years. At all time points, 98% of the patients were

"extremely satisfied or very satisfied" with the aesthetic results, and the surgeons categorized the outcomes as "very important or important improvement" in 96% of the cases.
Conclusions: Motiva Ergonomix SilkSurface devices provided **high patient satisfaction up to more than 5 years postoperatively** with very few complications. These data are consistent with other reports in the literature. The observed favorable outcomes might be attributed, at least in part, to the bioengineered "cell-friendly" surface of these implants.

Referenza [9]
Background: Numerous breast implants are used for breast reconstruction. Each has its advantages and disadvantages. Recent data regarding the link between BIA-ALCL and implant texture caused a significant paradigm shift toward the use of smooth round implants. Motiva Ergonomix, a silk-surface breast implant, is classified as a smooth implant. To date, there is little data regarding the use of this specific implant in breast reconstruction.
Objective: Describe a single surgeon's experience with Motiva Ergonomix, silk-textured, round implant for breast reconstruction.
Patients and methods: A retrospective chart review of all patients undergoing primary or revisionary breast reconstruction procedures, using Motiva Ergonomix, from January 2017 to January 2022. Patient demographics and medical status were extracted. Surgical data, including reconstructive technique, implant size, plane, use of acellular dermal matrix, and complications, were recorded. BREAST-Q questionnaires were completed.
Results: A total of 156 consecutive patients were retrieved (269 breasts). A total of 257 were direct-to-implant reconstructions and 12 expander-to-implant. Complications were described per breast. Capsular contraction, Baker grade 3-4, was seen in four breasts (1.49%) in the nonirradiated group and six (2.24%) in the irradiated group. Rippling was seen in 11 breast (4.08%), skin ischemia in 17 (6.31%), hematoma in 4 (1.49%), and seroma in 6 (2.23%). BREAST-Q: satisfaction with breast increased by a mean of 9.175 (60.7 points preoperatively to 69.875 postoperatively). Satisfaction with the implant was 6.52 out of 8.
Discussion: This cohort describes the current most extensive experience with Motiva Ergonomix implant used for reconstructive surgeries. Motiva Ergonomix breast implant endows a unique set of technologies to provide good results with a low complication rate.

Referenza [10]
Nessun abstract

Referenza [11]
Background: The emerging concerns around breast implant-associated anaplastic large cell lymphoma and other chronic inflammatory-related conditions have instigated a wider use of smooth devices.
Objectives: The authors aimed to present 6-year data following the introduction of Motiva implants (Establishment Labs Holdings Inc.; Alajuela, Costa Rica) into their previously texture-dominated practice. Additionally, the authors aimed to provide technical recommendations on how to efficiently incorporate these devices into surgical practice and minimize the learning curve.
Methods: Data of 1053 primary and secondary breast augmentations conducted between April 2015 and December 2020 in 2 centers (Victoriakliniken in Sweden and the European Institute of Plastic Surgery in Cyprus) were retrospectively evaluated to obtain data on chosen implant characteristics and complications that led to reoperation, prior to and following modifications to surgical practice in 2018.
Results: The data from 6 consecutive years demonstrate a low device-related complication rate with Motiva implants. In 2018, following adaptions in surgical practice, the complication rate significantly declined.
Conclusions: Motiva implants demonstrate a low complication rate and safety profile for women undergoing primary and secondary breast augmentation procedures. However, to reap the benefits of the antifibrotic profile, technical adaptions and optimal patient planning based on the patient and device characteristics are instrumental. Employing the key principles laid out in this study provides a means for delivering both clinically safe options to patients with aesthetically pleasing long-term results.

Referenza [12]
Background: Motiva Implants (Establishment Labs Holdings Inc.) are a novel family of silicone breast implants using cutting-edge technologies engineered to optimize aesthetic and safety outcomes.
Objectives: The authors sought to prospectively evaluate the safety and effectiveness of SmoothSilk/SilkSurface Motiva Implants over long-term follow-up.
Methods: Surgeons at a single plastic surgery center undertook a 10-year follow-up study of SmoothSilk/SilkSurface Motiva Implants in women who underwent primary breast augmentation. Safety was assessed through identification of complications on follow-up and through magnetic resonance imaging (MRI) in a representative sample. Effectiveness outcomes were assessed by surgeons and patients using Likert scales and a Quality of Life tool.
Results: Th**is article reports the 6-year safety and effectiveness outcomes. A total of 35 patients** were implanted between September and December 2010, and 71.9% of implants were placed submuscularly using inframammary incision. **During the 6-year follow-up, there were no occurrences of capsular contracture, rupture, double capsules, or late seroma.** MRI evaluation identified no signs of implant-related complications. Three revision surgeries were performed, all for aesthetic reasons; there were no implant replacements for medical reasons. The level of satisfaction for both patients and surgeons was high at all follow-up visits. Patient quality-of-life scores increased following breast augmentation by an average of 0.89% at 72 months.
Conclusions: The results of this prospective long-term follow-up study demonstrate the excellent safety and effectiveness of SmoothSilk/SilkSurface Motiva Implants in primary breast augmentation through 6 years of follow-up.

Referenza [13]

Background: Macrotextured anatomical implants are frequently used in aesthetic breast surgery; however, several safety concerns linked to this implant type have been raised recently. In an attempt to address these shortcomings, Motiva Ergonomix implants have been introduced. Here, the authors describe the current world's largest experience with these novel devices in aesthetic breast surgery and evaluate the postoperative outcome of 100 primary breast augmentations.
Methods: A retrospective assessment of 100 consecutive primary breast augmentation patients over a period of 3 years was conducted. Patients were followed for a minimum of 6 months postoperatively. Demographics, surgical data, and complications were recorded. In addition, a survey regarding the breast augmentation outcome was performed.
Results: The reasons for surgery were mainly hypoplasia (52 percent) and ptosis (28 percent). All implants were placed by means of an inframammary approach in a submuscular pocket, and the average implant volume was 370 cc (range, 150 to 700 cc) with mostly full projection (65 percent). **The revision rate was 7 percent**. **The authors observed four cases of implant malpositioning, one implant rupture, one implant exchange for aesthetic reasons, and one hematoma evacuation**. Nevertheless, the authors achieved a 100 percent satisfaction rate with the postsurgical outcome among both patients and surgeons.
Conclusions: Motiva Ergonomix implants provide reliable and satisfying results for both patients and surgeons. They can be used safely and effectively for aesthetic breast surgery. However, like all breast prostheses, Motiva Ergonomix implants are not completely free of complications and should be used only with advanced technique to achieve optimal results.

Referenza [14]*

Background: Silicone breast implants have been in use for breast augmentation for more than 50 years, but technological innovation has been lacking in implant design until recently.
Objectives: This study was designed to evaluate the complication and reoperation rates following breast augmentation utilizing the Motiva silicone breast implants.
Methods: This retrospective study evaluated the safety of Motiva implants **in 5813 consecutive cases of breast augmentation**. Implants with two different textured surfaces were evaluated: SilkSurface (nanotextured) and VelvetSurface (micro-textured).
Results: Implants were placed between April 2013 and April 2016. **A total of 44 complications were reported, with an overall complication rate of 0.76%,** and the rate of reoperation was 0.76% over an interval of 3 years. There were no late complications and no cases of primary capsular contracture. **No differences in complication rates were observed because of the implant date. However, among patients who received implants 300 to 499 cc in volume, complication rates were significantly lower with SilkSurface compared with VelvetSurface implants.** Advanced statistical analysis supported the validity of the low complication rate reported in this study.
Conclusions: Overall, these findings suggest that Motiva silicone breast implants are associated with very low rates of complication and reoperation, and that the nano-textured SilkSurface implant is associated with fewer complications than micro-textured implants.

*Paragraph extracted from the Results section: "The overall complication rate with SilkSurface implants was 0.36% (95% CI, 0.19% to 0.68%). By comparison, the complication rate with VelvetSurface implants was 1.06% (95% CI, 0.76% to 1.47%). Because the CIs for the two implant surfaces do not overlap, we can conclude that SilkSurface implants have a significantly lower total risk rate than VelvetSurface implants."

Referenza [15]

Background and objectives: We conducted this preliminary retrospective study to assess the short-term safety of silicone gel-filled breast implants (SGBIs) that are commercially available in Korean women.
Materials and methods:The current retrospective, observational study was conducted in a total of 2612 patients (n = 2612) who underwent augmentation mammaplasty using breast implants at our hospitals between 1 January 2017 and 31 August 2021.
Results: Overall, there were **a total of 248 cases** (9.49%) of postoperative complications; these include 112 cases of early seroma, 52 cases of shape deformation, 32 cases of CC, 12 cases of early hematoma, 12 cases of rupture, 12 cases of infection, 12 cases of stretch deformities with skin excess and 4 cases of rippling. Overall complication-free survival of the breast implant was estimated at 1564.32 ± 75.52 days (95% CI 1416.39-1712.32). Then, **the Motiva Ergonomix™ SilkSurface showed the longest survival** (1528.00 ± 157.92 days [95% CI 1218.48-1837.56]), **followed by the BellaGel® SmoothFine** (1458.4 ± 65.76 days [95% CI 1329.56-1587.28]), **the Sebbin® Sublimity** (1322.00 ± 51.20 days [95% CI 1221.64-1422.32]), **the BellaGel® Smooth** (1138.72 ± 161.28 days [95% CI 822.6-1454.84), **the Mentor® MemoryGel™ Xtra** (698.4 ± 52.64 days [95% CI 595.28-801.52]) **and the Natrelle® INSPIRA™** (380.00 ± 170.88 days [95% CI 45.04-714.96]) in the decreasing order. On subgroup analysis, both the Motiva ErgonomixTM and Mentor® MemoryGel™ Xtra showed no postoperative complications. However, the BellaGel® SmoothFine, Sebbin® Sublimity and BellaGel® Smooth showed incidences of 8.87%, 4.84% and 1.61%, respectively. A subgroup analysis also showed differences in incidences of postoperative complications between microtextured and smooth breast implants (15.18% vs. 16.67%).
Conclusions: In conclusion, our results indicate that diverse types of an SGBI are commercially available and their safety profile varies according to the manufacturer. Plastic surgeons should consider the safety profile of each device in selecting the optimal types of the device for Korean women who are in need of an implant-based augmentation mammaplasty. However, this warrants a single-surgeon, single-center study with long periods of follow-up.

Copia del documento può essere scaricata dal sito http://www.regione.toscana.it/-/prodotti-hta.

Redazione del report a cura del Centro Operativo, Decreto regionale n.17610 del 7 Settembre 2022.

Per ulteriori informazioni scrivere alla mail centro.operativo.htart@regione.toscana.it

A seguire la scheda tradotta automaticamente in Inglese come risulta dal software DeepL (http://www.deepl.com/translator)

RAPID HTA REPORT		
Request No.	**Date of request**	**Applicant**
293	20/04/2023	AOUP - Senology

Type of report	
New report	Yes
Updating a previous report	No
If updating, please state the reason:	

General technology data			
Trade name			
Sterile silicone breast implants Motiva Implants® Ergonomix® Round SmoothSilk®/SilkSurface®			
Generic name			
Ergonomic silicone breast implants			
Manufacturer name			
ESTABLISHMENT LABS			
Supplier name			
MOTIVA ITALY SRL			
RDM	**REF**		
13129XXX,1313XXX, 1322XXX, 1324XXX, 1832XXX.	-		
Type	**CE marking (date)**	**Risk class**	**FDA approval**
1	745219 R000 (24/05/2017)	Class III	No

CND
P060199 (Breast implants other)
Clinical problem and rationale for the request
Breast reconstruction and breast augmentation are the main reasons why women undergo plastic surgery. According to the American Society for Aesthetic Plastic Surgery (ASAPS), more than 100,000 reconstruction procedures and approximately 200,000 breast augmentation procedures were performed in the US in 2020 [1]. These procedures involve the implantation of silicone breast implants, the safety of which has often been debated. An association between anaplastic large cell lymphoma (ALCL) and breast implants has been discovered. However, this correlation seems to be more pronounced in certain types of devices, particularly those with a macro-structured surfacerather than in those with a smooth/nanostructured surface. The lower incidence of ALCL in implants with a smooth/nanostructured surface could be related to the lower inflammatory response, which would also result in a reduced risk of capsular contracture, but this is currently demonstrated in vitro [2-12].
Indications for use
Motiva Implant sterile silicone breast implants from Establishment Labs are indicated for the following procedures in female patients: - Breast reconstruction, including previous reconstruction to replace breast tissue removed due to cancer or trauma, or whose development has been compromised due to breast abnormalities, as well as revision surgery to correct or improve the results of a previous reconstructive surgery. - Breast augmentation for women aged 18 years or older, including previous augmentations to increase breast volume, and revision surgery to correct or improve the result of a previous additive surgery.
Target patient
Female patients in need of breast reconstruction; unilateral mastectomy candidates with particular breast conformation (medium-large volume, medium-high ptosis); female patients aged > 18 years in need of breast augmentation.

General technology data

Main competitors

Currently in use by the applicant are Siltex textured silicone gel breast implants.

Technological details

Description

The Motiva Implants Ergonomix Round SmoothSilk/SilkSurface family consists of devices constructed with successive cross-linked layers of silicone elastomer and a low diffusion barrier wrap with BluSeal Technology, which together provide the mechanical properties and integrity of the device. The surface of the envelope, SmoothSilk/SilkSurface, is classified as a smooth surface. These breast implants consist of a single-lumen round shell, a patch system and a silicone filler gel (ProgressiveGel Ultima). A radio frequency identification (RFID) microtransponder embedded in the gel is optional and available for all implant models. This microtransponder provides each device with a unique electronic serial number for traceability, which can be used to access a database containing breast implant information. Implants are available in a wide range of base widths, projections (profiles) and volumes.

Elements of Innovation

Motiva Ergonomix shows a low inflammatory response and a higher degree of biocompatibility than other competitors, due to the special and unique topography of the surface. This surface is considered, according to the UNI EN ISO 140607_2018 directive, concerning the classification of breast implant surfaces, to be a smooth surface (0 -> 10 mc) although not completely (3.09 microns). Such a surface could result in a lower incidence of ALCL, but the studies supporting this hypothesis are, to date, in vitro studies.

Another potentially important element is the fact that in cases of unilateral mastectomy on breasts with medium-large volume or medium-high ptosis the characteristics of the Progressive Ultima gel could determine a symmetry of shape and position with the surviving breast without intervening on the same with reduction mammaplasty or mastopexy, thus allowing a reduction in invasiveness and operating theatre time. Unfortunately, however, there is no citable data on the fact that Motiva Ergonomix implants allow contralateral symmetrization to be avoided.

Clinical and economic evidence

Clinical studies

A Pubmed search with the keyword "Motiva SilkSurface" revealed 21 articles, 7 of which were considered relevant [8-9,11-15]. Of these 7 studies, 1 [9] concerned the use of this prosthesis in patients undergoing breast reconstruction for cancer, while 6 concerned the use of this prosthesis for breast augmentation for aesthetic reasons [8,11-15].

A single surgeon's experience with Motiva Ergonomix round SilkSurface silicone implants in breast reconstruction over a 5-year period [9].

Since there is little evidence of the use of such an implant in breast reconstruction, the experience of a single centre is reported.

A retrospective review of records of patients undergoing primary or revision breast reconstruction procedures was conducted, using Motiva Ergonomix, from January 2017 to January 2022. Demographic and surgical data were extracted and BREAST-Q questionnaires were completed.

A total of 156 consecutive patients (269 sinuses) were recovered. 257 were *direct to implant* reconstructions and 12 *expander to implant*. Capsular contraction was found in 4 breasts (1.49%), rippling was observed in 11 breasts (4.08%), skin ischaemia in 17 (6.31%), haematoma in 4 (1.49%) and seroma in 6 (2.23%). Satisfaction with the implant was 6.52 out of 8.

A Single Centre's Clinical Experience With Ergonomix Breast Implants [8].

The present retrospective study reports the first experiences of a surgical centre with Motiva Ergonomix SilkSurface breast implants. A total of 356 patients (712 implants) received Ergonomix SilkSurface implants between April 2014

Clinical and economic evidence

and October 2018 from 3 different surgeons and the minimum follow-up was 12 months.
Only 6 major complications were observed: one ptosis at 12 months (0.14%) and 2 capsular contractures (0.28%), one at 14 months and one at 2 years. 98% of the patients were extremely or very satisfied with the aesthetic result obtained and the surgeons considered that there was a very important or important improvement in 96% of the cases.

Six-Year Evaluation of Motiva Round and Ergonomix SmoothSilk Surface Silicone Breast Implants: A Two-Centre, Two-Surgeon Outcome Analysis of 1053 Primary and Secondary Breast Augmentations and Mastopexy Augmentation [11].
Data from 1053 primary and secondary additive mastoplasties (2016 breasts) performed between April 2015 and December 2020 in 2 centres were retrospectively evaluated.
The overall complication rate at 6 years was 4.9% (52 cases). The predominant complication was inferior displacement of the implant below the original submammary fold in 1.6% (17 cases). Double projection, simmastia or implant rupture was found in 0.2% (2 patients). Rates of capsular contracture were low, 0.4% (4 cases) over 6 years. Patients experienced pain in 0.4% (4 cases). There were no cases of re-intervention or infection.

Six-Year Prospective Outcomes of Primary Breast Augmentation With Nano Surface Implants [12].
The objective of the study was to prospectively evaluate the safety and efficacy of SmoothSilk/SilkSurface Motiva implants (silicone breast implant family) in long-term follow-up.
Surgeons from a single plastic surgery centre undertook a 10-year follow-up study on implants. SmoothSilk/SilkSurface Motiva in women undergoing primary breast augmentation. This paper reports the results at 6 years. A total of 35 patients underwent implantation between September and December 2010 and 71.9% of the implants were placed via submuscular incision. During the 6-year follow-up, there were no cases of capsular contracture, rupture, double capsules or late seroma. MRI showed no implant-related complications. Three revision surgeries were performed for aesthetic reasons. No implant replacements were performed for medical reasons. The level of satisfaction for both doctors and patients was high at all follow-up visits. The patients' quality of life scores increased following breast augmentation by an average of 0.89% at 72 months.

Motiva Ergonomix Round SilkSurface Silicone Breast Implants: Outcome Analysis of 100 Primary Breast Augmentations over 3 Years and Technical Considerations [13].
In the present study, a retrospective evaluation was conducted on 100 patients who underwent primary breast augmentation surgery over 3 years. The patients were monitored for a minimum of 6 months after the operation. In addition, an interview on the outcome of the surgery was carried out.
The reasons for surgery were hypoplasia (52%) and ptosis (28%). All implants were placed through a submammary approach in a submuscular pocket with an average implant volume of 370 cc with almost complete projection (65%). The revision rate was 7%. Four cases of implant malpositioning, one implant rupture, one implant exchange for aesthetic reasons and one haematoma evacuation were observed. Despite this, a 100% satisfaction rate was achieved regarding the post-operative outcome for both patient and surgeon.

Preliminary 3-Year Evaluation of Experience With SilkSurface and VelvetSurface Motiva Silicone Breast Implants: A Single-Centre Experience With 5813 Consecutive Breast Augmentation Cases [14].
This retrospective study evaluated the safety of Motiva Implants in 5813 consecutive breast augmentation cases. Two different textured surfaces were evaluated: SilkSurface (nanostructured) and VelvetSurface (microstructured). The implants were placed between April 2013 and April 2016. A total of 44 complications were reported, with an overall complication rate of 0.76%. The re-intervention rate was 0.76% over 3 years. There were no late complications or cases of primary capsular contracture. No differences in complications were observed due to the date of implantation. However, among patients who received implants with volumes from 300 to 499 cc, complication rates were significantly lower with SilkSurface implants than with VelvetSurface.

Clinical and economic evidence
A Preliminary Retrospective Study to Assess **the Short-Term Safety of Traditional Smooth or Microtextured Silicone Gel-Filled Breast Implants in Korea** [15] **This is** a preliminary retrospective study to assess the short-term safety of commercially available silicone gel-filled breast implants implanted in Korean women. The observational, retrospective study was conducted on a total of 2612 patients who underwent breast augmentation between January 2017 and August 2021. Overall, there were 248 cases (9.49%) of postoperative complications: 112 of early seroma, 52 of deformity, 32 of capsular contraction, 12 of early haematoma, 12 of rupture, 12 of infection, 12 of stretch deformity with excess skin and 4 of rippling. Overall, the complication-free survival of the breast implant was estimated at 1,564.32 ± 75.52 days (95% CI 1416.39-1712.32). Motiva Ergonomix SilkSurface (nanostructured surface) showed the highest survival (1528.00±157.92 days [95% CI 1218.48-1837.56]) followed by BellaGel SmoothFine (1458.4±65.76 days [95% CI 1329.56-1587.28]), Sebbin Sublimity (1322.00 ± 51.20 days [95% CI 1221.64-1422.32]), BellaGel Smooth (1.138.72 ± 161.28 days [95% CI 822.6-1,454.84], Mentor MemoryGel Xtra (smooth surface) (698.4 ± 52.64 days [95% CI 595.28-801.52]) and Natrelle INSPIRA (380.00 ± 170.88 days [95% CI 45.04-714.96]) in descending order. Considering subgroups, both Motiva Ergonomix and Mentor MemoryGel Xtra showed no postoperative complications. However, BellaGel SmoothFine, Sebbin Sublimity and BellaGel Smooth showed incidences of 8.87%, 4.84% and 1.61%, respectively. A subgroup analysis also showed differences in the incidence of postoperative complications between microstructured and smooth breast implants (15.18% vs. 16.67%).
Ongoing clinical trials
A search on clinicaltrials.gov with the keyword "Motiva Ergonomix" revealed only one study: Study NCT05449587: multicentre, observational, single-arm study with a minimum of 160 patients undergoing breast implant surgery, 3 to 10 years postoperatively. Outcomes are the rate of silent implant rupture and patient satisfaction and quality of life. The study is in the enrolment phase and is scheduled to end in December 2023.
Guidelines
No Guidelines
Cost-effectiveness analysis
No cost-effectiveness analysis
HTA Report
The following Australian report is available: South Australian Policy Advisory Committee on Technology (SAPACT): Health Technology Assessment (HTA) Motiva® breast implants for breast reconstruction surgery [16]. This report expresses a limited recommendation for clinical use. Specifically, physicians are required to obtain informed patient consent and report clinical results of the device to the Australian Breast Implant Registry (ABIR) and/or TGA for monitoring purposes. The report points out that no peer-reviewed work has been published focusing on the outcomes of Motiva breast implants in breast reconstruction, only on breast augmentation; therefore, high-quality controlled studies with long-term data are needed to evaluate the safety, clinical and cost-effectiveness of this technology.
Expected benefits
The potential benefit from the use of prostheses with SilkSurface topography, characterised as smooth-surfaced prostheses, is a reduced inflammatory response and a consequent lower incidence of capsular contraction and ALCL, but this thesis is only supported by in vitro studies on the surface under investigation. Another potential benefit is in cases of unilateral mastectomy on breasts with medium-large volume or medium-high ptosis where the characteristics of the Progressive Ultima gel could allow symmetry of shape and position with the surviving breast without intervening on it with reduction mammaplasty or mastopexy. However, there is no citable data on whether Motiva Ergonomix implants allow contralateral symmetrization to be avoided.

Price and cost of therapy per patient			
Product (Manufacturer)	**Unit price (euro)**	**Therapy cost per patient (euro)**	**Annual requirements (No. pieces)**

Price and cost of therapy per patient			
Motiva Implants Ergonomix® (ESTABLISHMENT LABS)	600-650	600-1.300	80 (divided as follows: 35 for AOUP, 35 for AOUS, 10 for AVNO)

Price and cost of therapy per patient with existing treatment alternatives		
Product (Manufacturer)	**Unit price (euro)**	**Therapy cost per patient (euro)**
Smooth round silicone gel breast implants	315	315 to 630

Economic and organisational impact
The possible use of Motiva Ergonomix leads to an increase in expenditure as it is priced higher (twice as high) than comparator prostheses.

Reimbursability information			
Main diagnosis (ICD9-CM code)	**Intervention (ICD9-CM Code)**	**DRG code**	**Tariff (euro)**
174.X, 233.0; V52.4; 996.54	85.33/85.35; 85.53/85.54; 85.93	258; 461	3.044 (258); 2.613 (461)

Assessment of innovativeness (according to Regional Resolution N° 737/2022, link and N° 1244/2022 link)	
Innovative device (Y/N)	No
If yes, please indicate which Criteria 1, 2 and 3 are met:	

Summary data		
Request number	**Date of request**	**Applicant**
293	24/04/2023	AOUP - Senology and AOUS
Technology		
Motiva Implants® Ergonomix® Round SmoothSilk®/SilkSurface®		
Conclusions		
The Motiva Implants Ergonomix Round SmoothSilk/SilkSurface prosthesis consists of successive cross-linked layers of silicone elastomer and a low diffusion barrier shell with BluSeal Technology, which together provide the mechanical characteristics and integrity of the device. These breast implants consist of a single-lumen round shell, a patch system and a silicone filler gel (Ultima Progressive Gel). The surface of the envelope, SmoothSilk/SilkSurface, is classified as a smooth surface. Among the various studies analysed, only the one by Kaplan et al. 2023 [9] evaluates the use of this prosthesis for breast reconstruction in breast cancer patients, the other studies evaluate the use of Motiva Ergonomix for aesthetic reasons [8,10-15]. With regard to the limitations emerging from this evidence, the main problem is the total absence of comparisons with other prostheses in terms of efficacy and/or safety. The only partial exception is the study by Sforza et al. [14] in which, comparing the Ergonomix prosthesis with the VelvetSurface prosthesis, while no differences were observed in the incidence of complications in the overall population, in the subgroup of patients who received implants with a volume between 300 and 499 ml, the Ergonomix prosthesis showed a significantly lower incidence of complications; the significant p-value is, however, assumed since it is not explicitly reported.		

The potential benefits deriving from the use of prostheses with SilkSurface topography are twofold: 1) reduced inflammatory response and consequent lower incidence of capsular contraction and ALCL; 2) in cases of unilateral mastectomy on breasts with medium-large volume or medium-high ptosis, the characteristics of the Progressive Ultima gel could allow symmetry of shape and position with the surviving breast without operating on the same breast with reduction mammaplasty or mastopexy. Unfortunately, these benefits are not yet sufficiently documented; in fact, to date, only in vitro studies are available on the lower incidence of ALCL, while there is no trial on the possibility of not performing contralateral symmetrization. On the other hand, the price of Motiva Ergonomix is double the price of standard breast implants.

In conclusion, the CO expresses a favourable opinion subject to a reduction in the price of Motiva Ergonomix. In particular, considering that we want to express an openness to potential innovation, a price not exceeding 15% of the comparator price is accepted.

Date of report
04/09/2023 (updated 01/02/2024)
Author(s) of the report
Maria Rita Romeo
Referring pharmacist
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APPENDIX 1

The abstracts of References [8] to [15] can be seen in the Italian version of this document (pages 7 to 9).