Core Clinical Study
Reconstruction Cohort
Implant Removal *Without* Replacement

CORE STUDY - RECONSTRUCTION

Implant Removal Without Replacement

Patient ID	Reason for Explant	Source of Info	Implant Status at Time of Removal for Those That Led to Patient Discontinuation (i.e. ruptured or non-ruptured)	Complications Reported	Reason Implants Were Not Replaced
Left Implant	Decrease size Capsular contracture Implant malposition	Form 9	Not ruptured	Implant malposition Capsular contracture Breast cancer (date of onset is prior to implantation)	Replaced with McGhan style 410 (a non-Core study implant)
Left Implant	NI*	Form 9	Not ruptured	Breast cancer (date of onset is prior to implantation) Capsular contracture Implant malposition Hormonal therapy	Patient implanted with a non-Core study McGhan device by different physician
Right Implant	NI*	Form 9	NI*	Breast cancer (bilateral-date of onset is prior to implantation) Capsular contracture Implant malposition Inadequate inframammary crease	Unknown
Left Implant	Recurrent Cancer	Form 9	Not ruptured	Breast cancer (date of onset is prior to implantation) Swelling Eschar	Unknown
Both Implants	Suspected rupture	Form 9	Ruptured	Suspected rupture	Replaced with saline
Left Implant	Implant malposition Implant slipped through a small opening in the axilla to the patient's back	Form9	Not ruptured	Seroma Asymmetry	Unknown

CORE STUDY - RECONSTRUCTION

Implant Removal Without Replacement (cont.)

Patient ID	Reason for Explant	Source of Info	Implant Status at Time of Removal for Those That Led to Patient Discontinuation (i.e. ruptured or non-ruptured)	Complications Reported	Reason Implants Were Not Replaced
Right Implant	Capsular contracture Pain	Form 9	Not ruptured	Asymmetry Breast pain Capsular contracture	Replaced with McGhan style 10 (a non-Core study implant)
Right Implant	Capsular contracture	Form 9	Not ruptured	Swelling Redness Capsular contracture	Unknown
Left Implant	Asymmetry	Form 9	Not ruptured	Swelling Asymmetry Breast still firm	Replaced with Mentor implant
Both Implants	Inadequate widths of the device Inadequate volume (both bilateral)	Form 9	Not ruptured	Muscle spasms Breast cancer (date of onset is prior to implantation) Increase size (all bilateral)	Replaced with Mentor implants
Right Implant	Infection	Form 9	Not ruptured	Asymmetry Redness Irritation Breast cancer (date of onset is post-implantation)	Unknown
Left Implant	Cancer	Form 9	NI*	Swelling Breast cancer (date of onset is prior to implantation) Breast cancer recurrence (date of onset is post implantation)	Unknown

CORE STUDY - RECONSTRUCTION

Implant Removal Without Replacement (cont.)

Patient ID	Reason for Explant	Source of Info	Implant Status at Time of Removal for Those That Led to Patient Discontinuation (i.e. ruptured or non-ruptured)	Complications Reported	Reason Implants Were Not Replaced
Both Implants	Pain (bilateral)	Form 9	NI*	Breast pain (bilateral) Asymmetry Implant malposition (left) Paresthesia of extremities (bilateral)	Replaced with Mentor implants
Both Implants	Capsular contracture Pain (both bilateral)	Form 9	Not ruptured	Asymmetry Skin rash (bilateral) Tightness (right) Discomfort (bilateral)	Replaced with Mentor implants
Both Implants	Asymmetry	Form 9	Ruptured (right) Not ruptured (left)	Venous congestion (right) Suspected rupture (bilateral) Asymmetry	Replaced with Mentor implants
Right Implant	Pain Implant malposition	Form 9	Not ruptured	Swelling Implant malposition	Discomfort; Not satisfied

*NI = No information provided by site. Explant was performed by another physician.