Core Clinical Study
Revision Cohort

Implant Removal *Without* Replacement

CORE STUDY - REVISION

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
Both Implants	Capsular contracture (left) Scar encapsulation (left) Match left side (right)	Form 9	Not ruptured	Seroma (bilateral) Loss of skin sensation (left) Swelling (bilateral) Fat Necrosis (left) Capsular contracture (left)	Continuous problems with left breast
Both Implants	Indentation (left)	Form 7	Not ruptured	Swelling (bilateral) Seroma (left) Indentation (left)	Replaced with PIP implants
Both Implants	Suspected rupture (bilateral)	Form 9	NI*	Seroma (right) Lymphadenopathy (left) Implants possibly too large (bilateral)	Unknown
Both Implants	Implant visibility (right) Decrease size (left)	Form 9	Not ruptured	Implant visibility (right) Redness (right) Tenderness (right) Infection (right) Blister-like lesion involving inframammary fold area (right) Firmness (right)	Replaced with saline
Both Implants	Increase size (bilateral)	Form 9	NI*	None	Unknown

CORE STUDY - REVISION

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	Patient desires smaller breast implant (bilateral)	Form 9	Not ruptured	None	Replaced with Mentor Implants
Both Implants	Decrease size (bilateral)	Form 9	Not ruptured	None	Replaced with Mentor Implants
Both Implants	Patient desire for 410s (bilateral)	Form 9	Not ruptured	None	Replaced with McGhan style 410 (a non-Core study implant)
Left Implant	Pain (left)	Form 9	Not ruptured	Pain Breast cancer (date of onset is prior to implantation) Left arm pain	Unknown
Both Implants	Too big (bilateral)	Form 9	Not ruptured	None	Unknown

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