Core Clinical Study
Augmentation Cohort
Implant Removal *Without* Replacement

CORE STUDY - AUGMENTATION

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	Patient states that she is uncomfortable with the idea of having silicone in her body, so she will replace with saline (bilateral)	Form 15	NI*	Swelling (bilateral)	Patient states that she is uncomfortable with the idea of having silicone in her body, so she will replace with saline
Both Implants	Asymmetry Increase size Capsular Contracture (all bilateral)	Form 9	Not ruptured	Skin puckering around nipple Swelling Bruising Seroma Asymmetry Capsular contracture (all bilateral)	Replaced with saline
Both Implants	Decrease size Patient desires to switch to saline (both bilateral)	Form 9	Not ruptured	Swelling Capsular contracture Fluid accumulation (all complications left side only)	Patient desires to switch to saline
Both Implants	NI* (Forms 8 & 9 not completed)	NA	NI*	Swelling (bilateral)	Patient did not want implants any more
Both Implants	Capsular contracture (bilateral)	Form 9	Not ruptured	Capsular contracture (bilateral)	Replaced with Mentor implants

CORE STUDY - AUGMENTATION

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	Capsular contracture (bilateral)	Form 9	NI*	Fluid Accumulation (left only) Asymmetry Seroma (left only) Capsular contracture (left only) Capsule calcification (left only) Ptosis (bilateral)	Unknown
Both Implants	Increase size (bilateral)	Form 9	Not ruptured	None	Replaced with Mentor implants
Both Implants	Obtuse angle to the cleavage Multiple folding Inadequate fill (all bilateral)	Form 9	Not ruptured	Wrinkling / rippling (bilateral)	Replaced with Mentor implants
Both Implants	Implants are "heavier" than they used to be (bilateral)	Form 9	Not ruptured	Patient feels as though her implants are heavy (bilateral)	Unknown
Both Implants	Patient did not want implants anymore (bilateral)	Form 9	Not ruptured	None	Patient did not want implants any more
Both Implants	Change to saline (bilateral)	Form 9	NI*	None	Change to saline
Both Implants	Patient request (bilateral)	Form 9	Not ruptured	Asymmetry	Patient request

CORE STUDY - AUGMENTATION

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	Capsular contracture (bilateral)	Form 9	Not ruptured	Breast pain (left) Swelling (bilateral) Hypertrophic scarring (right) Capsular contracture (bilateral)	Unknown

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