

(b) (6)

U.S. Food and Drug Administration Center for Devices and Radiological Health (b) (6) 10903 New Hampshire Ave.

Silver Spring. MD 20903

(b) (6)

RE: Postmarket Surveillance (PS) Study: PS160001/R004 Annual Interim Postmarket Surveillance Report

Trade Name: Essure® System for Permanent Birth Control

Reference PMA: P020014

August 30, 2018

Global Regulatory Affairs 921 Parker Street Berkeley, CA 94710 Phone: (b) (6)

Dear (b) (6)

Reference is made to FDA's letter dated February 29, 2016 regarding order to conduct a postmarket surveillance study for Essure under Section 522 of the Federal Food, Drug and Cosmetic Act. Reference is also made to FDA's approval of the Essure 522 study plan on September 2, 2016.

Bayer is herewith submitting the 24-month Interim Postmarket Survelliance Report (see **Attachment 1**).

The information contained in this submission is considered confidential, and Bayer therefore requests protection of this information in accordance with 18 USC 1905, 21 USC 331 (1), 5 USC 522.

This submission is provided in accordance with the eCopy Program for Medical Device Submissions, Guidance for Industry and Food and Drug Administration Staff (October 10, 2013).

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Bayer looks forward to closely working with the FDA on this post market surveillance study. Should you require additional information, please feel free to contact (b) (6) or by email at (b) (6)

Company Confidential

Respectfully,

(b) (6)

ATTACHMENT 1: 24-Month Interim Postmarket Surveillance Report

cc: (b) (6)



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24-Month Interim Postmarket Surveillance Report

An open-label, non-randomized, prospective observational cohort study to assess post-procedural outcomes in two cohorts of women who chose to undergo either hysteroscopic sterilization (Essure®) or laparoscopic tubal sterilization

Bayer Study (b) (4)

Postmarket Surveillance Application #PS160001

Date of Report: 30 AUG 2018

Data Current to:

02 JUL 2018

Postmarket Surveillance Report BAY (b) (4)



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Table	Subject Accountability by Treatment Group (Full Analysis Set)
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	Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC ferred Term (Full Analysis Set)



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List of abbreviations

AE Adverse event FAS Full analysis set

HSG Hysterosalpingogram

LTS Laparoscopic tubal sterilization

MedDRA Medical Dictionary for Medical Activities

(b) (4)

PSV Pre-selection visit

SAE Serious adverse event SOC System organ class

TEAE Treatment-emergent adverse event

TVU Transvaginal ultrasound

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1. General Information

Postmarket Surveillance Application Number: PS160001

Sponsor Information 1.1

Name:

Bayer Healthcare LLC

Address:

30 AUG 2018

100 Bayer Blvd.

P.O. Box 915

Whippany, NJ 07981 USA

Contact Person:

(b) (6)

Telephone:

Email Address:

(b) (6)

1.2 **Product Information**

Device trade name and model number: Essure® System (ESS305)

Date of the 522 order: 29 FEB 2016

Date of postmarket surveillance plan approval: 02 SEP 2016

2. **Report Information**

Date of report: 30 AUG 2018

Data included in this report: clinical study

Type of submission: interim Postmarket Surveillance Report

Postmarket Surveillance Information 3.

3.1 **Study Purpose**

3.1.1 Goals

Study (b) (4) is an open-label, non-randomized, continuous enrollment, prospective observational, postmarket surveillance study of two cohorts of subjects who chose to undergo:



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- hysteroscopic sterilization (Essure System), or
- laparoscopic tubal sterilization.

3.1.2 Objectives

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3.1.3 Study Endpoints

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3.2 Study Population

The planned study population includes subjects of reproductive age, between 21 and 45 years of age, who have not been pregnant within the past 6 weeks.

The Essure study population group will include subjects who chose to undergo hysteroscopic sterilization and who meet the criteria as outlined in the most current approved version of the Essure Instructions for Use.



Subjects will be followed for a total of 36 months post-procedure. Table 1 provides the subject follow-up visit schedule.

Table 1 Subject Follow-up Visit Schedule

Time of Visit	Office Visit	Telephone Contact
) (4)		

3.3 Report Dates

The postmarket surveillance plan was approved by the Food and Drug Administration on 02 SEP 2016.

The data extract used for the tabulations provided in this report includes all data entered into the database as of 02 JUL 2018. Data are preliminary and will be updated with ongoing monitoring efforts.

3.4 Summary of Study/Surveillance Progress Milestones/Timeline Elements

3.4.1 Site and Subject Recruitment Status

The site and subject enrollment progress as of 02 JUL 2018 is shown below. A subject is considered to be enrolled after signing informed consent.

- number of sites contacted: approximately 8774
- number completing Questionnaire #1 (Interest): 421 (341: Yes; 50: Maybe; 30: No)



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- number completing Questionnaire #2 (Feasibility): 359
- number identified for pre-selection visit (PSV): 133
- number of PSVs completed: 104
- number of sites approved for participation: 90
- number of Institutional Review Board approvals: 74
- number of clinical sites activated (approved to begin screening): 67
 - o type of facilities (note: additional categories have been added to this section to reflect the verbatim response provided by sites for type of facility):
 - University Hospital: 12
 - Public/Private Hospital: 4
 - Research Center: 3
 - Private Practice: 30
 - Private Practice/Research Center: 11
 - Public/Private Hospital/Private Practice/Research Center: 2
 - Public/Private Hospital/University Hospital: 1
 - Public/Private Hospital/Private Practice: 1
 - University Hospital/Research Center: 1
 - University Hospital/Private Practice: 1
 - Integrated Care System: 1
- number of sites with subjects enrolled: 56
- subject accrual start date: 03 MAY 2017
- subject accrual completion date: target = to be determined
- number of subjects enrolled (signed informed consent): 575 (Essure: 236; LTS: 339)
- percentage of subjects reaching each designated study phase: see Section 3.4.2.
- On 20 JUL 2018, Bayer announced a business decision to discontinue sales of the Essure device effective 31 DEC 2018. Impact on subject recruitment is to be determined.



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3.4.2 Subject Disposition and Accounting

The disposition of subjects enrolled (signed informed consent) as of the 02 JUL 2018 data extract is shown in Table 2. Of the 236 subjects in the Essure group and 339 subjects in the LTS group who signed informed consent and entered the screening phase, (b) (4) and (b) (4) subjects, respectively, attended the procedure visit and of these, (b) (4) and (b) (4) subjects, respectively, had the procedure attempted. (b) (4)



A full accounting of subjects by treatment group and study phase is in Table 3.



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Table 2 Disposition – Overview (All Enrolled Subjects)

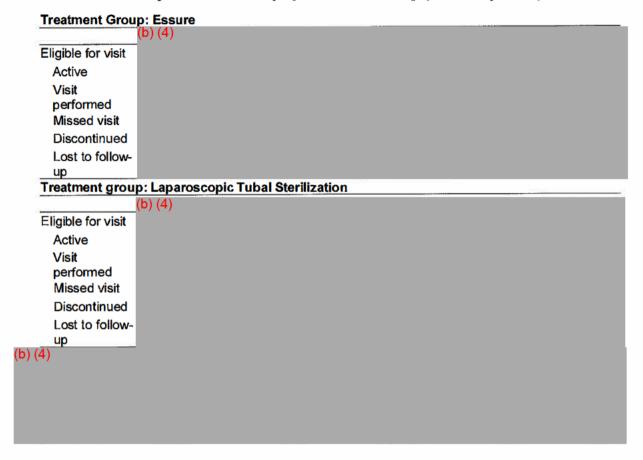
		Laparoscopic Tubal	
Disposition	Essure	Sterilization	Total
Number (%) of subjects enrolled	236	339	575
Screening Failures	(b) (4)		
Primary Reason			
Inclusion/exclusion criteria not met			
Lost to Follow-up			
Withdrawal by Subject			
Other			
Entered Procedure Phase			
No Procedure Attempted			
Procedure Attempted			
Told to Rely*			
Completed the End of Study visit			
Discontinued from the Study			
Primary Reason			
Pregnancy			
Lost to follow-up			
Withdrawal by Subject			
Other			





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Table 3 Subject Accountability by Treatment Group (Full Analysis Set)



3.5 Subject Demographics, Baseline Characteristics, and Medical History





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Table 4 Demographics, Baseline Characteristics and Medical History (Full Analysis Set)





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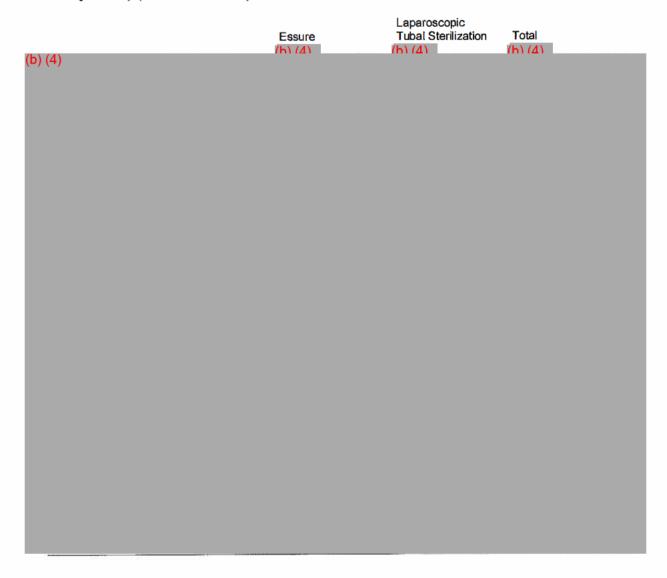
Table 4 Demographics, Baseline Characteristics, and Medical History (Full Analysis Set) (continued; 2 of 3)





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Table 4 Demographics, Baseline Characteristics, and Medical History (Full Analysis Set) (continued 3 of 3)



3.6 Procedure-Related Findings

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3.7 Interim Safety Results

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(b) (4)	

BAY (b) (4)



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Table 5 Overall Summary of Adverse Events (Full Analysis Set)

Essure Sterilization Total

(b) (4) (b) (4) (b) (4)

Number Number of Number of Number of Number of Of AEs Subjects (%) of AEs Subjects (%)

Laparoscopic Tubal

(b) (4)



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Table 5 Overall Summary of Adverse Events (Full Analysis Set) (continued; 2 of 3)

Laparoscopic Tubal Total Sterilization Essure Number Number of (b) (4) Number of (b) (4) Number Number of Number Subjects (%) of AEs of AEs Subjects (%) of AEs Subjects (%) (b) (4)





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Table 5 Overall Summary of Adverse Events (Full Analysis Set) (continued; 3 of 3)

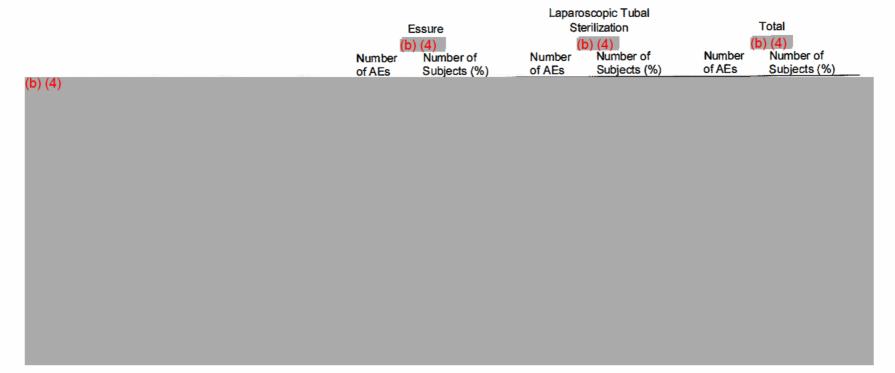
Laparoscopic Tubal Essure Sterilization Total Number Number of (b) (4) Number of Number Number of Number Subjects (%) Subjects (%) Subjects (%) of AEs of AEs of AEs (b) (4)



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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set)





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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 2 of 7)

Laparoscopic Tubal Sterilization Total **Essure** (b) (4)) Number of (b) (4) (b) (4) Number of Number Number of Number Number Subjects (%) Subjects (%) ofAEs of AEs Subjects (%) of AEs (b) (4)



Total

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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 3 of 7)

Essure

Number Number of Number of

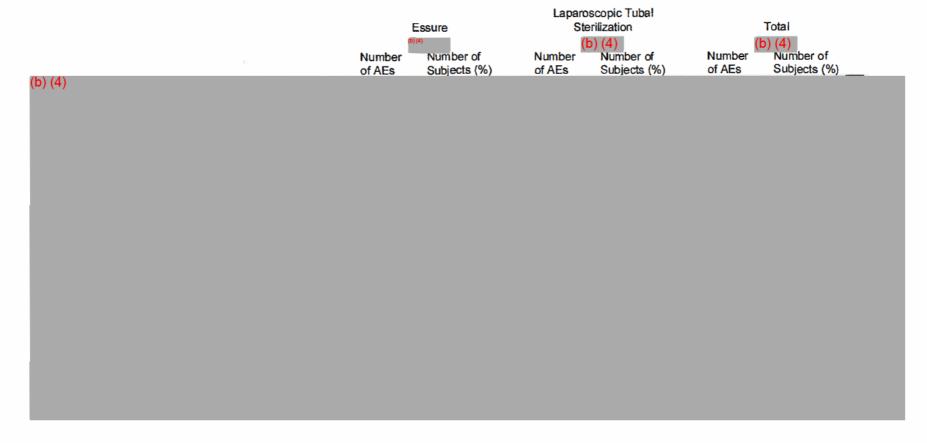
Laparoscopic Tubal

Sterilization



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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 4 of 7)





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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 5 of 7)

Laparoscopic Tubal Total Essure Sterilization (b) (4) (b) (4) (b) (4) Number of Number of Number of Number Number Number Subjects (%) of AEs Subjects (%) of AEs Subjects (%) of AEs (b) (4)



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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 6 of 7)

Total Sterilization Essure (b) (4) Number of Number Number of Number Number of Number of AEs Subjects (%) Subjects (%) of AEs Subjects (%) of AEs (b) (4)

Laparoscopic Tubal

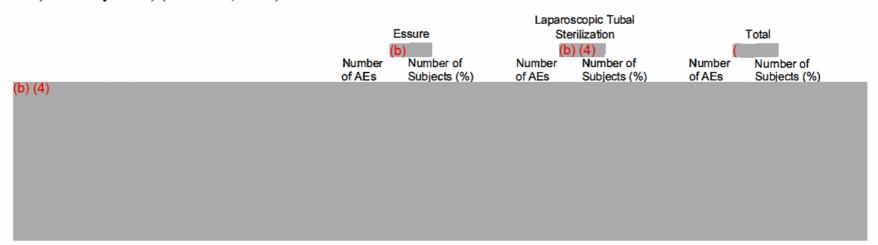




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Table 6 Subject Incidence of Treatment-emergent Adverse Events (TEAEs) by SOC and Preferred Term (Full Analysis Set) (continued; 7 of 7)





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4. Summary

(b) (4)	
A (b) (4)	data review was conducted on 23 AUG 2018. (b) (4)



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5. Appendix



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5.1 Adverse Events – Subject Listing (All Enrolled Subjects)

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(b) (4)

Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended						Causal rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
ldentifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

Footnotes please refer to the last page.





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended						Causal rel.			-
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(b) (4)										

Footnotes please refer to the last page.

BAY (b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/	•	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	Attended Steril- ization Procedure/ Attempted		Start Prior to	Adverse Event Start Date		Relation	Causal rel. to Pre- existing condition or Con			
Unique Subject	Steril- ization/	SOC/ Preferred	Index Event/	(Day)/ End Date		Procedure	Med or other			
Identifier/ Age/Race	Rely on Steril- ization	Term/ Reported Term	After Censor/ Serious AEOSI /Reason	(Day)/ Duration (davs)	Intensity	Type of Procedure	non-study proce- dures	Treatment of AE	Outcome	Comment

(b) (4)

Footnotes please refer to the last page.

BAY (b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Attended rel.	
Ob all	
Steril- to Pre-	
ization Start Adverse existing	
Procedure/ Prior Event condition	
Attempted to Start Date Relation or Con	
Steril- SOC/ Index (Day)/ to Med or	
ization/ Preferred Event/ End Date Procedure other	
Unique Subject Rely on Term/ After (Day)/ / non-study	
Identifier/ Steril- Reported Censor/ Serious Duration Type of proce- Treatment	
Age/Race ization Term AEOSI /Reason (days) Intensity Procedure dures of AE Outcome Com	ment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (Ali Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Jnique Subject	Rely on	Term/	After	(Day)/		1	non-study			
dentifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization `	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal		
	Attended							rel.		
	Steril-							to Pre-		
	ization		Start		Adverse			existing		
	Procedure/		Prior		Event			condition		
	Attempted		to		Start Date		Relation	or Con		
	Steril-	SOC/	Index		(Day)/		to	Med or		
	ization/	Preferred	Event/		End Date		Procedure	other		
Unique Subject	ct Rely on	Term/	After		(Day)/		1	non-study		
Identifier/	Steril-	Reported	Censor	/ Serious			Type of	proce-	Treatment	
(1.) (4)	ization	-	AFOSI	/Reason	(davs)	Intensity	- 4			

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	e/	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

I	Jnique Subject dentifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/ Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	late as it.	Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment	Outcome	0
	Age/Race	ization	Term	AEOSI /Reason		Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization Procedure/ Attempted		Start Prior to		Adverse Event Start Date	***	Relation to	Causal rel. to Pre- existing condition or Con Med or			
	Steril- ization/	SOC/ Preferred	Index Event/		(Day)/ End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study	e:		
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

(b) (4)	Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term		Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	ргосе-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) $\overline{(4)}$





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								·	Causal	·		
		Attended							rel.			
		Steril-							to Pre-			
		ization		Start		Adverse			existing			
		Procedure/		Prior		Event			condition			
		Attempted		to		Start Date		Relation	or Con			
		Steril-	SOC/	Index		(Day)/		to	Med or			
		ization/	Preferred	Event/		End Date		Procedure	other			
	Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
	Identifier/	Steril-	Reported	Censor/ Se	erious	Duration		Type of	proce-	Treatment		
/1.\	Age/Race	ization	Tem	AEOSI /R	Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended							Causal rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ S	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /	Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

(b) (4)	in control ((22,30)						20
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
	ization/	Preferred	Event/		End Date		Procedure	other			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	Attempted		to		Start Date		Relation	or Con			
							Dolotion				
	Procedure/	,	Prior		Event			condition			
	ization		Start		Adverse			existing			
	Steril-							to Pre-			
	Attended							rel.			
								Causal			



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

									Causal			
		Attended							rel.			
		Steril-							to Pre			
		ization		Start		Adverse			existing			
		Procedure/		Prior		Event			condition			
		Attempted		to		Start Date		Relation	or Con			
		Steril-	SOC/	Index		(Day)/		to	Med or			
		ization/	Preferred	Event/		End Date		Procedure	other			
Uniqu	e Subject	Rely on	Term/	After		(Day)/		/	non-study			
ldentif	ier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/R	lace	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment		
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(b) (4)											



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization Procedure/		Start Prior	Adverse Event			Causal rel. to Pre- existing condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/ Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel to Pre-existing condition or Con Med or other non-study proce-	Treatment		
Identifier/	Steril-	Reported				Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

				7.70				_			
								Causal			
	Attended		19					rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
		0001									
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment
4)											





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			*****
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

-							Causal			
	Attended						rei.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AFOSI /Reason		Intensity	Procedure	dures	of AF	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

		91					Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serio	us Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Rea	son (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou	s Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reas	on (days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization		Start	Adverse		Causal rel. to Pre- existing			
	Procedure/ Attempted Steril- ization/	SOC/ Preferred	Prior to Index Event/	Event Start Date (Day)/ End Date	Relation to Procedure	condition or Con Med or other			
Unique Subject Identifier/	Rely on Steril- ization	Term/ Reported	After Censor/ Serious	(Day)/ Duration	/ Type of	non-study proce- dures	Treatment	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group:(b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	e/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Reiv on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	on (days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Attende Steril- ization Proced Attemp Steril- ization/ Unique Subject Rely on	ure/ ed SOC/ Preferred	Start Prior to Index Event/ After	Adverse Event Start Date (Day)/ End Date (Day)/	Relation to Procedure /	rel. to Pre- existing condition or Con Med or other non-study		
Identifier/ Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment	

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reaso	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	/	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization Procedure/		Start Prior	Adverse Event		Dolotion	Causal rel. to Pre- existing condition or Con			
Unique Subject Identifier/ Age/Race	Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	to Index Event/ After Censor/ Serious AEOSI /Reasoi	Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Med or other non-study proce- dures	Treatment of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

										the second secon
							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	e/	Prior	Event			condition			
	Attempted	l	to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reason	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment
/L\ / /\										

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment			
						1-1	• •			0.4	0	
Age/Race	ization	Tem	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment	_

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Serious AEOSI /Reaso		Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment	
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(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	•	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou	s Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	on (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

-	Attended							Causal rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	/	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
0.0	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	2)	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ S	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /F	Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

: 1 					110			Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	1	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Walling F	Attended Steril- ization		Start		Adverse			Causal rel. to Pre- existing			
	Procedure		Prior		Event		Dolotion	condition			
	Attempted Steril-	SOC/	to Index		Start Date (Day)/		Relation to	or Con Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject	Attended Steril- ization Procedure Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported		Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	latanait.	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment	Outcome	Commont
Age/Race	ization	Term	AEOSI			Intensity	Procedure		of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term		Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment	
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(b) (4)

Postmarket Surveillance Report





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/ Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment			
Age/Race	ization	Term	AEOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment	



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Steril- SOC/ Index (Day)/ to Med or ization/ Preferred Event/ End Date Procedure other Unique Subject Rely on Term/ After (Day)/ / non-study Identifier/ Steril- Reported Censor/ Serious Duration Type of proce- 1 Age/Race ization Term AEOSI /Reason (days) Intensity Procedure dures or



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group(b) (4)

12 - 12 - 11 - 10 - 1							Causal			
	Attended						rel.			
	Steril-						to Pre			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Relv on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/	1	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
4	ization	Term	AEOSI	/Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment	Æ.	
dentifier/	Steril-	Reported					_ * 1	ргосе-			
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Commen



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Seriou AEOSI /Reas	Adverse Event Start Date (Day)/ End Date (Day)/ is Duration on (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment	
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(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group(b) (4)

						CLASS MINERAL PROPERTY AND ADDRESS OF THE PERSON NAMED IN COLUMN TO PE			- COUNTY OF THE PARTY OF THE PA	
							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seri			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Rea	ason (days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(A)										



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril ization	SOC/ Preferred Tem/ Reported Term	Start Prior to Index Event/ After Censor/ S AEOSI //	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b) (4)										

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

, v - 10,110,1							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	e/	Prior	Event			condition			
	Attempted	1	to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

4	"	111.77						Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	1	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Se	erious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /R	Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

		1876	- D- A2111				Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Raœ	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group:(b) (4)

**	Attended Steril- ization		Start	Adverse		300	Causal rel. to Pre- existing			
	Procedure/ Attempted		Prior to	Event Start Date		Relation	condition or Con			
Unique Subject	Steril ization/ Rely on	SOC/ Preferred Term/	Index Event/ After	(Day)/ End Date (Day)/		to Procedure /	Med or other non-study			
ldentifier/ Age/Race	Steril- ization	Reported Term	Censor/ Serio AEOSI /Rea		Intensity	Type of Procedure	proce- dures	Treatment of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race (b) (4)	ization/ Rely on Steril- ization	Preferred Term/ Reported Term	Event/ After Cen s or/	Serious /Reason	End Date (Day)/ Duration	Intensity_	Procedure / Type of Procedure	other non-study proce- dures	Treatment of AE	Outcome	Comment
	Attended Steril- ization Procedure/ Attempted Steril-	SOC/	Start Prior to Index		Adverse Event Start Date (Day)/		Relation to	causal rel. to Pre- existing condition or Con Med or			



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

2	5-5507		***		- INIPAR			Causal			
	A Granda d							rel.			
	Attended										
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
			Censor/ S	Sorious	Duration		Type of	proce-	Treatment		
Identifier/	Steril-	Reported					_**			Outroms	C
Age/Race	ization	Term	AEOSI /I	Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

3	223000000							Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Se	rious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Re	eason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

). 27(8							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	-512	57.0000					Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

								Causal			
		Attended						rel.			
		Steril-						to Pre-			
		ization		Start	Adverse			existing			
		Procedure/		Prior	Event			condition			
		Attempted		to	Start Date		Relation	or Con			
		Steril-	SOC/	Index	(Day)/		to	Med or			
		ization/	Preferred	Event/	End Date		Procedure	other			
	Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
	Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
	Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
- \	/4\			712007 77100001	(44,72)				0.712	- Caroomio	

(b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

37.72	Attended Steril- ization		Start		Adverse			Causal rel. to Pre- existing			
	Procedure/ Attempted Steril- ization/	SOC/ Preferred	Prior to Index Event/		Event Start Date (Day)/ End Date		Relation to Procedure	condition or Con Med or other			
Unique Subject Identifier/ Age/Race	Rely on Steril- ization	Term/ Reported Term	After Censor/	Serious /Reason	(Day)/ Duration	Intensity	/ Type of Procedure	non-study proce- dures	Treatment of AE	Outcome	Comment
(b) (4)											



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			30000000
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index							
				(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	on (days)	Intensity	Procedure	•	of AF	Outcome	Comment
) (A)										

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

•						Causal			
	Attended					rei.			
	Steril-					to Pre-			
	ization		Start	Adverse		existing			
	Procedure	/	Prior	Event		condition			
	Attempted		to	Start Date	Relation	or Con			
	Steril-	SOC/	Index	(Day)/	to	Med or			
	ization/	Preferred	Event/	End Date	Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/	1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days) Intensi	ity Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

: : : : : : : : : : : : : : : : : : :							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group(b) (4)

							Causa			
	Attended						ref.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	•	Prior	Event:			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group(b) (4)

S.— HAMI. 1911							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Seriou AEOSI /Reas	Adverse Event Start Date (Day)/ End Date (Day)/ us Duration on (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AF	Comment	
) (4)	ization	rem	AEOSI /Reas	on (davs)	mensilv	Procedure	dures	Of AF	Comment	

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	<i>l</i>	Prior	Event			condition :			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reasor	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

		7,000	11.00				Causal	-		1000
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	ргосе-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	Attended Steril- ization Procedure/ Attempted		Start Prior		Adverse Event		Relation	rel. to Pre- existing condition		
	Attempted		to		Start Date		Relation	or Con		
	Steril-	SOC/	Index		(Day)/		to	Med or		
	ization/	Preferred	Event/		End Date		Procedure	other		
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study		
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	ргосе-	Treatment	
Aαe/Raœ	ization	Tem	AEOSI	/Reason	(davs)	Intensity	Procedure	dures	of AF	
(b) (4)										

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Outcome Comment

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Treatment Group: (b) (4)

Attended					Causal rel.
Steril-					to Pre-
ization		Start	Adverse		existing
Procedure/		Prior	Event		condition
Attempted		to	Start Date	Relation	or Con
Steril-	SOC/	Index	(Day)/	to	Med or
ization/	Preferred	Event/	End Date	Procedure	other

Unique Subject Rely on (Day)/ Term/ After non-study Identifier/ Censor/ Serious Duration Steril-Reported Type of Treatment proce-

Age/Race ization AEOSi /Reason (days) Term Procedure dures ofAE Intensity

 $(b)(\overline{4})$

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

								Causal			
	Attended					W		rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
2	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment
(b) (4)											

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Serious AEOSI /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment	
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(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

A TOTAL PROPERTY.						- 54.00.000	Causal			
	Attended						rel.			
	Steril-						to Pre			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
	ization	Tem	AEOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

						Causal	
	Attended					rel.	
	Steril-					to Pre-	
	ization		Start	Adverse		existing	
	Procedure/		Prior	Event		condition	
	Attempted		to	Start Date	Relation	or Con	
	Steril-	SOC/	Index	(Day)/	to	Med or	
- 23	ization/	Preferred	Event/	End Date	Procedure	other	
Unique Subject	Rely on	Tem/	After	(Day)/	1	non-study	
Identifier/	Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

$A \setminus A \setminus A$	Unique Subject Identifier/ Age/Race (b) (4)	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ S AEOSI /F	Serious Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment	
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term		Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment	
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(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Unique Subject Identifier/ Age/Race (b) (4)	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Serious AEOSI /Reasor		Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

2			Tanavarov Malar				Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	e/	Prior	Event			condition			
	Attempted	l	to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	Attended Steril- ization Procedure/ Attempted Steril- ization/	SOC/ Preferred	Start Prior to Index Event/		Adverse Event Start Date (Day)/ End Date		Relation to Procedure	causal rel. to Pre-existing condition or Con Med or other			
					End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(b) (4)											



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization Procedure/ Attempted Steril- ization/	SOC/ Preferred	Start Prior to Index Event/	Adverse Event Start Date (Day)/ End Date	Relation to Procedure	Causal rel. to Pre- existing condition or Con Med or other	
		Preferred		End Date	Procedure	other	
Unique Subject	Rely on	Term/	After	(Day)/	/	non-study	
Identifier/	Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

2								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/	<i>(</i>	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor	/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	Attended							Causal rel.		9	
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subje	ct Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
		•	/Reason	davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported		Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration	lahara ika	Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment	Out		
Age/Race	ization	Term	AFOSI	/Reason	(davs)	Intensity	Procedure	dures	of AF	Outcome	Comment	H



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ · Age/Race	Attended Steril- ization Procedure, Attempted Steril- ization/ Rely on Steril- ization		Start Prior to Index Event/ After Censor/ Serious AEOSI /Reaso	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment	2
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(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Serious	Adverse Event Start Date (Day)/ End Date (Day)/		Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non study	Treatment		
Unique Subject	Rely on	Term/	After		(Day)/		/	non study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(b) (4)											

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Serio AEOSI /Reas	 Intensity	Relation to Procedure / Type of Procedure	Causal rel, to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment _
(b) (4)									=



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group:(b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
	ization	Term	AEOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	7.4111			1,00	Pale		Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	d .	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	n (days)	Intensity_	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attanded					100		Causal			
	Attended Steril-							rel. to Pre-			
	ization		Start		Adverse			existing			
	Procedure	<i>1</i>	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

() — — — — — — — — — — — — — — — — — — —		71.70					Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
		-	AEOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

(b) (4)	Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI		Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Age/Race ization Term AEOSI /Reason (days) Intensity Procedure dures of AE Outcome Comment (b) (4)	Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Ser AEOSI /Re		te e	Relation to Procedure / Type of Procedure	non-study proce-	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril-						Causal rel. to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

()							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serio	us Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Rea	son (days)	Intensity	Procedure	dures	of AE	Outcome	Comment
(4)										



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	1000							Causal			
	Attended				754			rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure/		Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
	ization	Tem	AFOSI	/Reason	(davs)	Intensity	Procedure	dures	of AF	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

					in a willing 12 out on	and the second	Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	ſ	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days) I	ntensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proœ-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Lara del Constituto de la Constituto de	HYPACE		MMMCP1=Collaboration				Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou			Type of	proce-	Treatment		
(4)	ization	Tem	AFOSI /Reaso		Intensity	Procedure	dures	of AF	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Ž!	7.7						Causal			
	Attended				14.		rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

-							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
		Term	AFOSI /Reason	(davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI /Reaso	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

Postmarket Surveillance Report BAY^(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	ization/ Rely on Steril-	SOC/ Preferred Term/ Reported Term	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of	Causal rel. to Pre- existing condition or Con Med or other non-study proce-	Treatment	
(b) (4)									

Postmarket Surveillance Report BAY^(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reasor	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	Attended Steril- ization		Start		Adverse	330		Causal rel. to Pre- existing			
	Procedure/ Attempted Steril-	SOC/	Prior to Index		Event Start Date (Day)/		Relation to	condition or Con Med or			
Unique Subject	ization/ Rely on	Preferred Term/	Event/ After		End Date (Day)/		Procedure /	other non-study			
Identifier/ Age/Race	Steril- ization	Reported Term	Censor/ S AEOSI /	Serious Reason	Duration	Intensity_	Type of Procedure	proce- dures	Treatment of AE	Outcome	Comment

(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

-							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

			7A.0011					Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure.	/	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proœ-	Treatment		
Age/Race	ization	Term	AEOSI	Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

Postmarket Surveillance Report BAY (b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After	(Day)/		1	non study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reasor	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

Postmarket Surveillance Report BAY(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

	!!! ? !!				200 200		Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	1ndex	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
		Term	AFOSI /Reaso	n (davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

Postmarket Surveillance Report BAY(b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

	Attended Steril- ization Procedure/ Attempted		Start Prior to		Adverse Event Start Date	A. M.	Relation	Causal rel. to Pre- existing condition or Con			
Unique Subject Identifier/ Age/Race	Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Index Event/ After Censor/	Serious /Reason	(Day)/ End Date (Day)/ Duration	Intensity	to Procedure / Type of Procedure	Med or other non-study proce- dures	Treatment of AE	Outcome	Comment

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

			_	•			Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reaso	n (days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

Postmarket Surveillance Report BAY (b) (4)





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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term		Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment	
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(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group	(b)	(4)
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Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term		Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
(b) (4)	ization	Telli	AEOSI	/Neasun	(uays)	THEHSILV	Procedure	dures	OI AE	Outcome	Comment

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

								Causal			yure I/
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	/	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Tem/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Tem	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

						22/ (XVXXII) ——————————————————————————————————	Causal	VAT==:():	=10111111111111111111111111111111111111	
	Attended	Ÿ					rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure/		Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
		0001								
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason		Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

								Causal			
	Attended							rel.			
	Steril-							to Pre-			
	ization		Start		Adverse			existing			
	Procedure	1	Prior		Event			condition			
	Attempted		to		Start Date		Relation	or Con			
	Steril-	SOC/	Index		(Day)/		to	Med or			
	ization/	Preferred	Event/		End Date		Procedure	other			
Unique Subject	Rely on	Term/	After		(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Seriou			Type of	proce-	Treatment		
		•	AFOSI /Reas	nn (davs)	Intensity	••	'	of AF	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

						Causal	
	Attended					rel.	
	Steril-					to Pre-	
	ization		Start	Adverse		existing	
	Procedure/	•	Prior	Event		condition	
	Attempted		to	Start Date	Relation	or Con	
	Steri -	SOC/	Index	(Day)/	to	Med or	
	ization/	Preferred	Event/	End Date	Procedure	other	
Unique Subject	Rely on	Term/	After	(Day)/	1	non-study	
Identifier/	Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

							Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	/	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		/	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reasor	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

			12		- 200007	Causal	110.7000		
	Attended					rel.			
	Steril-					to Pre-			
	ization		Start	Adverse		existing			
	Procedure	/	Prior	Event		condition			
	Attempted		to	Start Date	Relation	or Con			
	Steril-	SOC/	Index	(Day)/	to	Med or			
	ization/	Preferred	Event/	End Date	Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/	1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious		Type of	proce-	Treatment		
Age/Race	ization	Term	AEOSI /Reason	n (days) Intensi	31	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group:(b) (4)

							Causal			
							rel.			
Steril-							to Pre-			
ization		Start		Adverse			existing			
Procedure/		Prior		Event			condition			
Attempted		to		Start Date		Relation	or Con			
Steril-	SOC/	Index		(Day)/		to	Med or			
ization/	Preferred	Event/		End Date		Procedure	other			
Rely on	Term/	After		(Day)/		1	non-study			
Steril-	Reported	Censor/	Serious	Duration		Type of	proce-	Treatment		
ization	Term	AEOSI	/Reason	(days)	Intensity	Procedure	dures	of AE	Outcome	Comment
	Procedure/ Attempted Steril- ization/ Rely on Steril-	Steril- ization Procedure/ Attempted Steril- ization/ Rely on Term/ Steril- Reported	Steril- ization Start Procedure/ Prior Attempted to Steril- SOC/ Index ization/ Preferred Event/ Rely on Term/ After Steril- Reported Censor/	Steril- ization Start Procedure/ Prior Attempted to Steril- SOC/ Index ization/ Preferred Event/ Rely on Term/ After Steril- Reported Censor/ Serious	Steril- ization Start Adverse Procedure/ Prior Event Attempted to Start Date Steril- SOC/ Index (Day)/ ization/ Preferred Event/ End Date Rely on Term/ After (Day)/ Steril- Reported Censor/ Serious Duration	Steril- ization Start Adverse Procedure/ Prior Event Attempted to Start Date Steril- SOC/ Index (Day)/ ization/ Preferred Event/ End Date Rely on Term/ After (Day)/ Steril- Reported Censor/ Serious Duration	Steril- ization Start Adverse Procedure/ Prior Event Attempted to Start Date Relation Steril- SOC/ Index (Day)/ to ization/ Preferred Event/ End Date Procedure Rely on Term/ After (Day)/ Steril- Reported Censor/ Serious Duration Type of	Attended Steril- ization Start Prior Attempted Steril- SOC/ Index Ization/ Rely on Term/ Steril- Reported Attempted Frior Fri	Attended Steril- ization Start Adverse existing Procedure/ Attempted to Start Date Relation or Con Steril- ization/ Preferred Event/ End Date Procedure other Rely on Term/ After (Day)/ Steril- Reported Censor/ Serious Duration Type of proce- Treatment	Attended Steril- ization Start Adverse existing Procedure/ Attempted to Start Date Relation or Con Steril- ization/ Preferred Event/ End Date Procedure other Rely on Term/ After (Day)/ Steril- Reported Censor/ Serious Duration Type of proce- Treatment

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

						Causal	-107		
	Attended					rel.			
	Steril-					to Pre-			
	ization		Start	Adverse		existing			
	Procedure	:/	Prior	Event		condition			
	Attempted		to	Start Date	Relation	or Con			
	Steril-	SOC/	Index	(Day)/	to	Med or			
	ization/	Preferred	Event/	End Date	Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/	1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious	Duration	Type of	proce-	Treatment		
		Term			,,,			Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ Serio	Adverse Event Start Date (Day)/ End Date (Day)/ ous Duration son (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre-existing condition or Con Med or other non-study procedures	Treatment of AE	Outcome	Comment
(b) (4)	izauon	Telli	ALUSI /Rea	aut (dava)	mensity	Flocedare	uures	UIAL	Outcome	Comment

Postmarket Surveillance Report BAY (b) (4)



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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

Unique Subject Identifier/	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril-	SOC/ Preferred Term/ Reported	Start Prior to Index Event/ After Censor/	Serious	Adverse Event Start Date (Day)/ End Date (Day)/ Duration		Relation to Procedure / Type of	Causal rel. to Pre-existing condition or Con Med or other non-study proce-	Treatment	
, -	•	Paparted	Concorl	Sorious	2 * * * * * * * * * * * * * * * * * * *		Type of	•	Treatment	
							_ / 1	•	rreautient	
Ane/Race	ization	Term	AEOSE	/Reason	(davs	Intensit	Procedure	dures		

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group (b) (4)

Unique Subject Identifier/ Age/Race	Attended Steril- ization Procedure/ Attempted Steril- ization/ Rely on Steril- ization	SOC/ Preferred Term/ Reported Term	Start Prior to Index Event/ After Censor/ AEOSI	Serious /Reason	Adverse Event Start Date (Day)/ End Date (Day)/ Duration (days)	Intensity	Relation to Procedure / Type of Procedure	Causal rel. to Pre- existing condition or Con Med or other non-study proce- dures	Treatment of AE	Outcome	Comment
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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Treatment Group: (b) (4)

			8972	77-324			Causal			
	Attended						rel.			
	Steril-						to Pre-			
	ization		Start	Adverse			existing			
	Procedure	1	Prior	Event			condition			
	Attempted		to	Start Date		Relation	or Con			
	Steril-	SOC/	Index	(Day)/		to	Med or			
	ization/	Preferred	Event/	End Date		Procedure	other			
Unique Subject	Rely on	Term/	After	(Day)/		1	non-study			
Identifier/	Steril-	Reported	Censor/ Serious			Type of	proce-	Treatment		
(4)			AEOSI /Reaso	n (davs)	Intensity	Procedure	dures	of AE	Outcome	Comment

(b) (4)

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Listing 14.3.4/2 Adverse Events - Subject Listing (All Enrolled Subjects)

Footnotes:

Race is identified as: A = Asian, B = Black, W = White, AI = American Indian or Alaska Native, NH = Native Hawaiian or Other Pacific Islander, NR = Not Reported, MUL = Multiple. The unit of 'Age' is years. '(Day)' is the day relative to the index event date.

Y=Yes, N=No

AEOSI = adverse event of special interest

(b) (6)

From: (b) (6)

Sent: Friday, August 31, 2018 11:26 AM

To: (b) (6) Cc: (b) (6)

Subject: PS160001/R4 - Bayer Healthcare, LLC - email receipt

Trade Name: Essure System for Permanent Birth Control

Document Number: PS160001/R4

Dated: August 30, 2018 Received: August 31, 2018

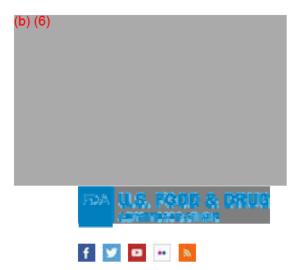
Dear (b) (6)

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your section 522 postmarket surveillance (PS) 2 year report. Within 60 days of the receipt date, FDA will notify you in writing of the decision.

Please be sure that future correspondence regarding your 522 PS study is sent to the attention of (b) (6)

If you have any procedural or policy questions concerning postmarket surveillance requirements, please contact (D) (6)

Thank you,



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(b) (4)

(b) (6)

From: (b) (6)

Sent: Thursday, December 20, 2018 12:10 PM

To: (b) (6) Cc: (b) (6)

Subject: FDA Decision - Bayer Healthcare, LLC - PS160001/R4

Dear (b) (6) :

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your section 522 postmarket surveillance (PS) study report PS160001/R4. This report is for the Postmarket Surveillance Study.

We have determined that you have sufficiently met the reporting expectations for the above report.

Advisory

- 1. Please be advised that your study status will be marked as "Progress Adequate" on the Section 522 Postmarket Surveillance Studies webpage (www.fda.gov/522studies).
- 2. Please be advised that due to the changing nature of the device sales and study enrollment rate, the reporting schedule has been changed to include a 30-month interim report, due March 4, 2019.

(b)(4)

Your next scheduled report is due March 4, 2019.

Thank you,



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MEMORANDUM

Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002

Date: December 20, 2018

From: (b) (6)

Subject: PS160001/R004

Essure System for Permanent Birth Control, Bayer Pharma AG 522 Study Requirement Name: Postmarket Surveillance Study

Epidemiologic Review of Postmarket Surveillance (PS) Study Interim Report

PS Order: Date of PS Order: February 29, 2016

ODE/OIR Document(s) on which the PS order was issued: P020014

To: (b) (6)

Through: (b) (6)

Conclusion/Recommendation:

The interim report (PS160001/R004) can be accepted.

522 Requirement Progress Status: Progress Adequate

Purpose:

The purpose of this memorandum is to present the epidemiologic review for the 12-month 522 Postmarket Surveillance (PS) Study Interim Report for the Essure System for Permanent Birth Control submitted by Bayer Pharma AG.

This memo includes:

- background information
- PS study protocol overview
- · the review and assessment of the interim study results
- PS study tracking information
- overall conclusions and recommendations

PS160001/R004 Review of 522 Interim Report

any applicable deficiencies.

Background:

Device Description

A. Essure System Components

The Essure System is comprised of the Essure micro-insert, a disposable delivery system, and a disposable split introducer.

Essure Micro-Insert

The Essure micro-insert is a spring-like device that consists of a stainless steel inner coil, a nickel titanium (Nitinol) expanding outer coil, and polyethelene terephthalate (PET) fibers. The PET fibers are wound in and around the inner coil. The micro-insert is 4 cm in length and 0.8mm in diameter in its wound down configuration. When released from the delivery system, the outer coil expands to 1.5 to 2.0 mm in diameter to anchor the micro-insert in the varied diameters and shapes of the fallopian tube. The spring-like device is intended to provide the necessary anchoring forces during the acute phase of device implantation (3 months post-micro-insert placement), during which time the PET fibers are eliciting tissue in-growth into the coils of the Essure micro-insert and around the PET fibers.

The Essure Micro-insert is provided attached to the delivery wire, in a wound-down configuration. The delivery wire is composed of a nitinol core wire, which is ground at the distal end to result in a flexible, tapered profile. The device is constrained by the release catheter, which is sheathed by a flexible delivery catheter. A black positioning marker on the delivery catheter aids in proper placement of the device in the fallopian tube.

The delivery handle controls the device delivery and release mechanism. The thumbwheel on the delivery handle retracts both the delivery catheter and the release catheter. The button allows the physician to change the function of the thumbwheel from retracting the delivery catheter to retracting the release catheter. The delivery wire is detached from the micro-insert by rotating the system.

Split Introducer

The split introducer is placed into the sealing cap of the working channel of the hysteroscope, and is intended to help protect the Essure Micro-insert as it is being passed through the sealing cap of the hysteroscope working channel.

- B. Mechanism of Action
- 1. Placement at Utero-Tubal Junction (UTJ)

The Essure Micro-insert is intended for placement into the fallopian tube with the implant portion of the device spanning the utero-tubal junction (UTJ). For purposes of micro-insert placement, the UTJ is defined as the portion of the fallopian tube, just as it enters the uterus. Placement at the UTJ is expected

to aid in anchoring since it most consistently represents the narrowest portion of the fallopian tube. Expulsion of the Essure Micro-insert has occurred when micro-insert placement was too proximal. If the device is placed without any trailing portion of the device in the uterus, then direct visualization of device location is not possible.

2. Tissue In-Growth

The effectiveness of the Essure Micro-insert in preventing pregnancy is believed to be due to a combination of the space-filling design of the device and a local, occlusive, benign tissue response to the PET fibers. The tissue response is the result of a chronic inflammatory and fibrotic response to the PET fibers. It is believed that the tissue ingrowth into the device caused by the PET fibers results in both device retention and pregnancy prevention.

3. Permanency of Tubal Occlusion (and Sterilization)

The long-term nature of the tissue response to the Essure micro-insert is not known. The majority of the clinical data regarding PET in the fallopian tube is based on 12-24 months of implantation, with little data at 36 months. Therefore, beyond 24 months, the nature of the cellular fibrotic response and the ability of the response and the device to maintain occlusion are not known.

Indications for Use

The Essure System is indicated for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes.

PS Order

On September 24, 2015, FDA convened a <u>meeting</u> of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee (see <u>transcript</u>), and the panel recommended additional data collection via postmarket surveillance. On February 29, 2016, FDA issued a <u>522 order</u> for the Essure Permanent Birth Control System.

PS Study Protocol Overview:

(b)(4)		

(b) (4)		

Study Element	Description		
Real-World Evidence	N/A		
(RWE) Study Design	en-label, non-randomized, prospective observational cohort study of o cohorts of subjects who chose to undergo either hysteroscopic erilization (Essure) or laparoscopic tubal sterilization.		
Study Hypothesis	There is no hypothesis testing.		
Study Population	The study population will include subjects of reproductive age, between 21 and 45 years of age* who have not been pregnant within the past 6 weeks. The study population will include women who chose to undergo hysteroscopic sterilization (Essure) and who meet the criteria as outlined in the Essure Instructions for Use (IFU).		
	(b)(4)		
	Women seeking laparoscopic tubal sterilization must be considered appropriate surgical candidates by the investigator.		
Sample Size	2,800 women (1,400 per arm) enrolled at 50-75 sites.		
	(b)(4)		
Study Endpoints	Follow-up measures will include adverse event assessment, medical history including gynecological procedures, patient reported outcome (PRO) measures for chronic pelvic pain and abnormal uterine bleeding, bloodwork for women with certain adverse events, and analysis of removed Essure devices.		
	Key Endpoints: Pain: The proportion of subjects reporting AEs of chronic lower abdominal and/or pelvic pain after insertion of Essure System (ESS305) (b) (4)		
	Bleeding: The proportion of subjects reporting AEs of abnormal uterine		

Study Element	Description
	bleeding after insertion of Essure System (b) (4)
	Total incidence of new onset or worsening abnormal bleeding events will be based on AE reporting.
	bleeding events will be based on AL reporting.
	Hypersensitivity/allergy/autoimmune disorders: The proportion of
	subjects with adjudicated new onset (b) (4)
	allergic/hypersensitivity reactions (b) (4)
	Proportion of subjects undergoing invasive gynecologic surgery (b)
	; including Essure insert removal(b) (4)
	Essare insert removal.
	Additional endpoints:
	Patient reported outcome measures (b) (4)
	Rates of AEs
Length of Follow-up and	(b) (4)
Frequency of Follow-up Assessments	36 months.
Assessments	30 months.
	(b)(4)
Enrollment Plan and	(b) (4)
Follow-up Measures	
	(b) (4)
Statistical Plan	



Timeline for Study Implementation (approved on September 2, 2016: PS160001/A002)

Milestone:	Date:	
Expected date of study initiation	September 2016	
Expected monthly number of study sites with IRB approvals	Approximately 8 sites/month	
Expected date of initiation of subject enrollment	May 2017	
Expected number of subjects enrolled per month	Approximately 78 patients/month (when all sites activated)	
Expected date of enrollment completion	May 2020	
Expected date of study follow-up completion	May 2023	
Expected date for final report submission	September 2023	

(b)(4)

PS Study Interim Status/Results and Assessments:

Interactive Review was conducted to obtain updated information about enrollment status and safety findings; see Attachment 1 and Attachment 2 for IR exchanges.

Study Elements

Number of IRB Approvals

Description

- As of July 2, 2018: 74
- As of September 17, 2018 (interactive review): 76
- As of October 24, 2018 (interactive review): 76

Assessment

Since the last interim report (PS160001/R003, data cutoff December 1, 2017), the number of IRB approvals has increased from 56 to 74 sites.
 The protocol specifies that 50-75 sites will be enrolled, and the study has met this goal. Acceptable.

Number of study sites enrolled

Description

- As of July 2, 2018: 67 sites have been activated, 56 sites have enrolled subjects.
- As of September 17, 2018 (interactive review): 67 sites have been activated, 58 sites have enrolled subjects. (b)(4); 63 sites are still open.
- As of October 24, 2018 (interactive review): 67 sites have been activated, 60 sites have enrolled subjects. (b)(4) ; 63 sites are still open.

Assessment

- The previous version of the protocol specifies that 50-75 sites will be enrolled. (b)(4)
- Since the last interim report (PS160001/R003, date of data cutoff December 1, 2017), the number of sites enrolled and activated has increased from 49 to 67 sites. The study has met the previous goal of 50-75 sites, and may now enroll additional sites, towards the new goal of up to 90 sites. Acceptable.

Number of subjects enrolled

Description

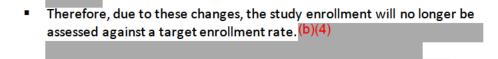
- Enrollment began on May 3, 2017.
- As of July 2, 2018: 575/2800 (20.5%), including 236/1400 (16.9%) in

Essure arm and 339/1400 (24.2%) in BTL arm.

- As of September 17, 2018 (interactive review): 691/2800 (24.7%), including 269/1400 (19.2%) in Essure arm and 422/1400 (30.1%) in BTL
- As of October 24, 2018 (interactive review): 750/2800 (26.8%), including 282/1400 (20.1%) in Essure arm and 468/1400 (33.4%) in BTL arm.

Assessment

On July 20, 2018, the manufacturer publicly announced that sales of Essure will cease after December 31, 2018. Enrollment into the 522 study is dependent on real world sales, and will cease once Essure sales/procedures cease; this almost certainly means that the study will not achieve the target sample size of 1400 patients per arm. (b)(4)



The enrollment rate has decreased to approximately 45 subjects per month (combined between both arms). This is likely due to the sponsor's announcement regarding the future cessation of sales of Essure. Although the rate is decreasing, the study is still enrolling new subjects into both arms, as agreed by FDA and the sponsor. The enrollment rate is acceptable.

Follow-up rate

Description
(b) (4)

(b) (4)			
(b) (4)			
(b) (4)			



Summary of Interim Study Results for the 522 Webpage (updated on April 25, 2018) (b)(4)

	Description	
Number of study sites enrolled	As of December 3, 2018, 791 patients have been enrolled	
	(293 in the Essure arm and 498 in the laparoscopic tubal	
	ligation arm).	
Number of subjects enrolled	As of December 3, 2018, 67 sites have been enrolled. 63 sites	
	are open for enrollment.	

PS Study Tracking Information:1. What is the Overall Study Status? Check only one.

	Plan Pending	FDA has not approved the study protocol, and it has been less than 6 months since issuance of the order.
	Plan Overdue	FDA has not approved the study protocol, and it has been 6 months or more since issuance of the order.
	Study Pending	The protocol has been approved, but no subjects have been enrolled.
Х	Progress Adequate	The study has begun, and the study progress is consistent with the protocol (e.g., meeting enrollment schedule, follow-up rates, endpoints evaluated).
	Progress Inadequate	The study has begun, but the study progress is inconsistent with the protocol (e.g., not meeting enrollment schedule, missing timepoint evaluations, poor follow-up rates, not all endpoints evaluated).

Completed	The sponsor has fulfilled the condition of approval, and FDA has closed the study. This is a final study status.	
Terminated	The sponsor has not fulfilled or cannot fulfill the condition of approval (e.g., study questions are no longer relevant, sponsor withdraws PMA, data cannot answer 522 question), and, after all appropriate efforts to fulfill the condition of approval have been exhausted, FDA has terminated the study. This is a final study status.	
Other	Used when the study status does not fit another category (e.g., not marketing the device and have no plans to market the device, change in ownership underway, redesigning device and need PMA approval prior to use in a PAS, pending separate study being used to address condition of approval). This is an interim study status.	

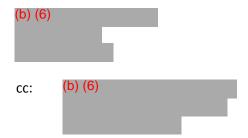
Deficiency List:

None

Advisory

- 1. Please be advised that your study status will be marked as "Progress Adequate" on the Section 522 Postmarket Surveillance Studies webpage (www.fda.gov/522studies).
- 2. Please be advised that due to the changing nature of the device sales and study enrollment rate, the reporting schedule has been changed to include a 30-month interim report, due March 4, 2019.





Document History:

Date	Activity	Initials
10/25/18	Drafted	(b) (6)
10/25/18	Reviewed with	
	comments	
10/26/18	Revised	
10/30/18	Reviewed/Cleared	
12/20/18	Finalized	



Attachment List

Attachment 1: Interactive Review Response (September 28, 2018)

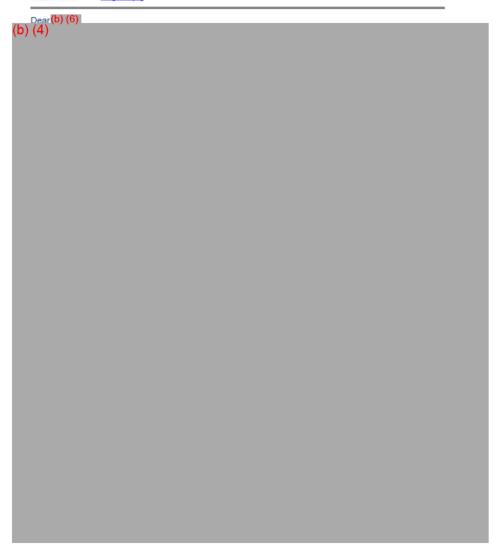
Attachment 2: Interactive Review Response (October 24, 2018)

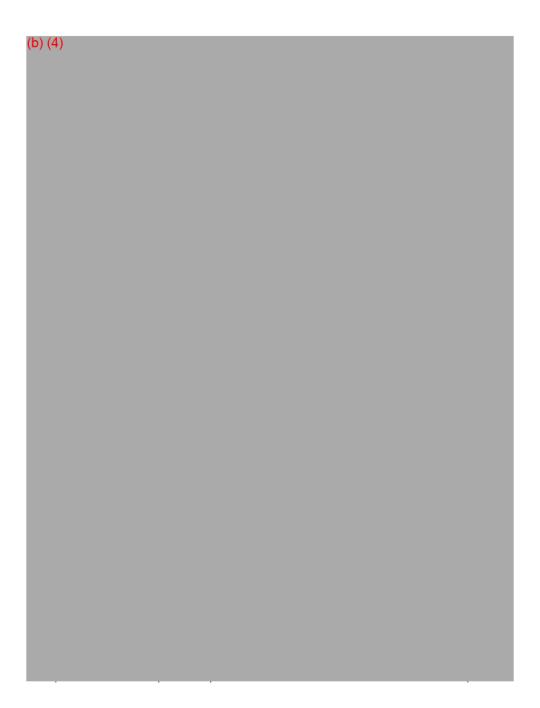
Attachment 3: Interactive Review Response (December 5, 2018)

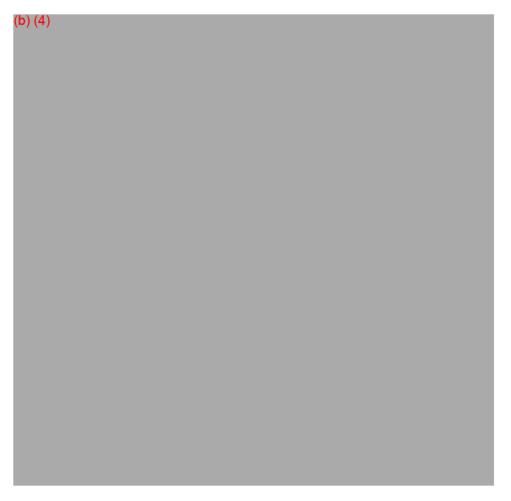
Attachment 1: Interactive Review Response (September 28, 2018)

From: To: Cc: Subject: Date: Attachments: (b) (6)

RE: PS160001/R004 Interactive Review Request (reply requested by 9/18) Friday, September 28, 2018 7:27:59 PM Image001.png







Thank you, **(b) (6)**

Freundliche Grüße / Best regards,

(b) (6)

Bayer U.S. LLC Development, Pharmaceuticals Essure & Devices 921 Parker Street Berkeley CA 94710 United States (b)(6)

Web: http://www.bayer.us

From: (b) (6) Sent: Monday, September 17, 2018 1:20 PM

To: (b) (6) Cc:

Subject: RE: PS160001/R004 Interactive Review Request (reply requested by 9/18)

Dear(b) (6)

Please see the response to Query #1 and #5.

- The date of database cutoff for the report is July 2, 2018, and therefore the enrollment
 information is out of date. Please provide an enrollment update with the following information:
 number of sites approved for participation, number of IRB approvals, number of clinical sites
 activated and open for enrollment, number of sites with subjects enrolled, and number of
 subjects enrolled (by arm).
 - · Number of sites approved for participation: 90
 - Number of IRB approvals: 76
 - Number of clinical sites activated and open for enrollment: 67 activated, 63 open for enrollment
 (b) (4)
 - Number of sites with subjects enrolled: 58
 - Number of subjects enrolled (by arm): Essure 269; LTS 422



Thank you, (b) (6)

Freundliche Grüße / Best regards,

(b) (6)

Bayer U.S. LLC
Development, Pharmaceuticals
Essure & Devices
921 Parker Street
Berkeley CA 94710
United States
(b)(6)

Web: http://www.bayer.us

From: (b) (6)
Sent: Tracday Sentember 11, 2018 12:49 PM
To: (b) (6)
Cc:
Subject: PS160001/R004 Interactive Review Request (reply requested by 9/18)
Importance: High

Dear (b) (6)

I am reviewing PS160001/R004, and I have a couple of questions I would like to resolve interactively. Please address the following questions:





Please send your responses via email by September 18, 2018. Please let me know if you have any questions or concerns.

Thank you!





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Signal Management Program: <u>link</u> Division of Epidemiology: <u>link</u>

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Attachment 2: Interactive Review Response (October 24, 2018) To: Cc: Subject: RE: PS160001/R004 Interactive Review Request (reply requested by 9/18) Date: Wednesday, October 24, 2018 2:29:54 PM Attachments: image001.png Dear (b) (6) Please see the enrollment update below. Number of sites approved for participation: 90 Number of IRB approvals: 76 Number of clinical sites activated and open for enrollment: 67 activated, 63 open for enrollment (b) (4) Number of sites with subjects enrolled: 60 Number of subjects enrolled (by arm): Essure – 282; LTS – 468 Thank you, (b) (6) Freundliche Grüße / Best regards, (b) (6) Bayer U.S. LLC Development, Pharmaceuticals Essure & Devices 921 Parker Street Berkeley CA 94710 United States (b)(6)Web: http://www.bayer.us From: (b)(6) Sent: Tuesd To: (b)(6) Subject: RE: P5160001/R004 Interactive Review Request (reply requested by 9/18) $_{Dear}(b)(6)$

(b) (4)







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Signal Management Program: link Division of Epidemiology: link

Attachment 3: Interactive Review Response (December 5, 2018)

(b)(6) From: Cc: Subject: RE: PS160001/R004 Interactive Review Request Wednesday, December 05, 2018 12:32:35 PM Date: Attachments: image001.png (b)(6)Dear As discussed on the call on Nov. 30th, an enrollment update is included below. As of December 3, 2018. Number of sites approved for participation: 90 Number of IRB approvals: 76 (b)(4)Number of clinical sites activated and open for enrollment: 67 activated, 63 open for enrollment (b) (4) Number of sites with subjects enrolled: 60 Number of subjects enrolled (by arm): Essure - 293; LTS - 498 Freundliche Grüße / Best regards, (b)(6)Bayer U.S. LLC Development, Pharmaceuticals Essure & Devices

Web: http://www.bayer.us

921 Parker Street Berkeley CA 94710 United States