

# Clinical Trial Approval Process in Colombia

Safety and Performance Study of the [REDACTED] (the "Study")

Sponsor: [REDACTED] | Product: [REDACTED]

## Study Budget

Version No. 2.0 Colombia-CEDIUL

Date: Sep 12, 2019

### Price per Subject

Prices are in USD

No. Subjects: 20

Study Activity Lists	
General Assessment	USD Cost / Activity
<b>Pre-Procedure</b>	
Invitation to enroll in the Study	\$12.00
Screening worksheet completed	\$12.00
Assessment of a competent annulus	\$12.00
Patient informed consent signed	\$12.00
Pre-procedure worksheet completed	\$12.00
Release of medical information **	\$15.00
Medical history **	\$20.00
Medications & dosage **	\$15.00
Physical exam **/**	\$20.00
Laboratory assessment (blood work)	\$20.00
Serum pregnancy test (female patients only)	\$12.00
Vital signs assessment	\$20.00
12 lead ECG	\$30.00
Pre-procedure CT	\$600.00
Baseline MRI T2 and T1rho (endplate status & adjacent levels)	\$600.00
Radiographs (standing lateral neutral)	\$50.00
Radiographs (AP & standing lateral: flexion, extension) - Assessment of the mobility of the treated segment	\$50.00
Assessment of low back pain score (VAS)	\$12.00
Oswestry disability questionnaire (ODI)	\$12.00
Pain diary information (record of pain medications)	\$12.00

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Operative	
Intra-operative fluoroscopy	\$300.00
Implantation	\$3,500.00
Operative worksheet completed	\$20.00
Anesthesiologist	\$0.00
Post-procedure	
Post-procedure worksheet completed	\$10.00
6-month follow-up procedure worksheet completed	\$15.00
12-month follow-up procedure follow-up completed	\$15.00
MRI T2 (endplate status & adjacent levels)	\$600.00
Confirm next appointment	\$5.00
Medical history **	\$15.00
Medications & dosage **	\$15.00
Physical exam **/**	\$15.00
Serum pregnancy test (female patients only)	\$12.00
Radiographs (standing lateral neutral)	\$50.00
Radiographs (AP & standing lateral: flexion, extension) - Assessment of the mobility of the treated segment	\$50.00
Assessment of low back pain score (VAS)	\$12.00
Oswestry disability questionnaire (ODI)	\$12.00
Pain diary information (record of pain medications)	\$12.00
	\$6,206.00

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Study Specialists' Fees	
Principal investigator	\$20.00
Study coordinator	\$20.00
Radiologist	\$180.00
Anesthesiologist	\$125.00

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Safety and Performance Study of the R [REDACTED] "Study")

Sponsor: [REDACTED] | Product: T [REDACTED]

### Study Budget

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No. Subjects 20

Study Schedule of Events									
General Assessment	Enrollment Start	Screening-1 (imaging)	Screening-2 (annulus)	Pre-operative Evaluation	Surgery Date	Discharge	12-week Evaluation (+/- 7 days)	26-week Evaluation (+/- 14 days)	52-week Evaluation (+/- 28 days)
	t-40 days	t - 36 days	t - 28 days	t - 14 days	t=0 days	t=0, +1 or +2 days	t + 85 days	t + 184 days	t + 364 days
	Per Subject								
<b>Pre-Procedure</b>				<b>GO / NO-GO?</b>					
Invitation to enroll in the Study	\$20.00								
Screening worksheet completed				\$12.00					
Assessment of a competent annulus			\$12.00						
Patient informed consent signed	\$12.00								
Pre-procedure worksheet completed									
Release of medical information **	\$15.00								
Medical history **	\$20.00								
Medications & dosage **	\$15.00								
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Laboratory assessment (blood work)		\$20.00							
Serum pregnancy test (female patients only)		\$12.00							
Vital signs assessment		\$20.00							
12 lead ECG		\$30.00							
Pre-procedure CT			\$600.00						
Baseline MRI T2 and T1rho (endplate status & adjacent levels)		\$600.00							
Radiographs (standing lateral neutral)		\$50.00							
Radiographs (AP & standing lateral: flexion, extension) - Assessment of the mobility of the treated segment		\$50.00							
Assessment of low back pain score (VAS)	\$12.00								
Oswestry disability questionnaire (ODI)	\$12.00								
Pain diary information (record of pain medications)	\$12.00								

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	t-40 days	t - 36 days	t - 28 days	t - 14 days	t=0 days	t=0, +1 or +2 days	t + 85 days	t + 184 days	t + 364 days
<b>Operative</b>									
Intra-operative fluoroscopy					\$300.00				
Implantation					\$3,500.00				
Operative worksheet completed					\$20.00				
<b>Post-procedure</b>									
Post-procedure worksheet completed						\$10.00	\$10.00	\$10.00	\$10.00
6-month follow-up procedure worksheet completed								\$15.00	
12-month follow-up procedure follow-up completed									\$15.00
MRI T2 (endplate status & adjacent levels)						\$600.00	\$600.00	\$600.00	\$600.00
Confirm next appointment		\$5.00	\$5.00	\$5.00		\$5.00	\$5.00	\$5.00	
Medical history **									\$15.00
Medications & dosage **									
Physical exam **/**									\$15.00
Serum pregnancy test (female patients only)									\$12.00
Radiographs (standing lateral neutral)						\$50.00	\$50.00	\$50.00	\$50.00
Radiographs (AP & standing lateral: flexion, extension) - Assessment of the mobility of the treated segment								\$50.00	\$50.00
Assessment of low back pain score (VAS)						\$12.00	\$12.00	\$12.00	\$12.00
Oswestry disability questionnaire (ODI)						\$12.00	\$12.00	\$12.00	\$12.00
Pain diary information (record of pain medications)							\$12.00	\$12.00	\$12.00

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	t-40 days	t - 36 days	t - 28 days	t - 14 days	t=0 days	t=0, +1 or +2 days	t + 85 days	t + 184 days	t + 364 days
<b>SubTotal price on General Assesment per visit</b>	\$138.00	\$787.00	\$617.00	\$17.00	\$3,820.00	\$689.00	\$701.00	\$766.00	\$803.00
<b>SubTotal price per subject</b>									<b>\$8,338.00</b>

Study Specialists' Fees									
	Enrollment Start	Screening-1 (imaging)	Screening-2 (annulus)	Pre-operative Evaluation	Surgery Date	Discharge	12-week Evaluation (+/- 7 days)	26-week Evaluation (+/- 14 days)	52-week Evaluation (+/- 28 days)
	t-40 days	t - 36 days	t - 28 days	t - 14 days	t=0 days	t=0, +1 or +2 days	t + 85 days	t + 184 days	t + 364 days
Per Subject									
Principal investigator	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00
Study coordinator	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00	\$20.00
Radiologist		\$180.00				\$180.00	\$180.00	\$180.00	\$180.00
Anesthesiologist					\$125.00				
<b>SubTotal price of specialists' fees per visit</b>	\$40.00	\$220.00	\$40.00	\$40.00	\$165.00	\$220.00	\$220.00	\$220.00	\$220.00
<b>SubTotal price of specialists' fees per subject</b>									<b>\$1,385.00</b>

TOTAL									
	Enrollment Start	Screening-1 (imaging)	Screening-2 (annulus)	Pre-operative Evaluation	Surgery Date	Discharge	12-week Evaluation (+/- 7 days)	26-week Evaluation (+/- 14 days)	52-week Evaluation (+/- 28 days)
	t-40 days	t - 36 days	t - 28 days	t - 14 days	t=0 days	t=0, +1 or +2 days	t + 85 days	t + 184 days	t + 364 days

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Study Schedule of Events									
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	Per Subject								
SubTotal price on General Assesment per visit	\$138.00	\$787.00	\$617.00	\$17.00	\$3,820.00	\$689.00	\$701.00	\$766.00	\$803.00
SubTotal price of specialists' fees per visit	\$40.00	\$220.00	\$40.00	\$40.00	\$165.00	\$220.00	\$220.00	\$220.00	\$220.00
<b>Total price per visit</b>	<b>\$178.00</b>	<b>\$1,007.00</b>	<b>\$657.00</b>	<b>\$57.00</b>	<b>\$3,985.00</b>	<b>\$909.00</b>	<b>\$921.00</b>	<b>\$986.00</b>	<b>\$1,023.00</b>
<b>Total price per subject</b>	<b>\$9,723.00</b>								

<b>PRE APPROVAL TECHNICAL ASPECTS</b>	
INTERNAL ETHICS COMMITTEE (Include all meetengs for [REDACTED])	\$800.00
TECHNIQUE PERFORMANCE PRE-PROCEDURE (PHANTOM/SIMULATOR) Suggested requirement by Scientific Ethics Committee for First In Huma	\$2,300.00