

*10/13 changes*

*10/14 changes*

*10/17 changes*

*September 2025*

**GORE PFO GSO CONJOINT**

**QUANTITATIVE HCP QUESTIONNAIRE**

|  |  |
| --- | --- |
| **RECRUITMENT QUOTAS** | **TOTAL** |
| Interventional Cardiologists | N=100 |
| **TOTAL** | **N=100** |

|  |  |
| --- | --- |
| **PROCEDURE VOLUME** | **TOTAL** |
| Low  *(hS8=1)* | n=15-35 |
| Moderate  *(hS8=2)* | n=15-35 |
| High  *(hS8=3)* | n=15-35 |

|  |  |
| --- | --- |
| **GORE USAGE** | **TOTAL** |
| Gore user  *(~~S8r2>0~~ S11r2=1 or 2)* | Minimum of n=30 |
| Gore non-user  *(~~S8r2=0~~ S11r2=3, 4, or 5)* | Minimum of n=30 |

|  |  |
| --- | --- |
| **AMPLATZER USAGE** | **TOTAL** |
| Amplatzer user  *(~~S8r1>0~~ S11r1=1 or 2)* | Minimum of n=30 |
| Amplatzer non-user  *(~~S8r1=0~~ S11~~r2~~ r1=3, 4, or 5)* | Minimum of n=30 |

|  |  |
| --- | --- |
| **YEARS IN PRACTICE (TRACKING)** | **TOTAL** |
| 3-5 years  *(S5=3-5)* | -- |
| 6-10 years  *(S5=6-10)* | -- |
| 11+ years  *(S5=11+)* | -- |

**Screening:**

We are conducting interviews among healthcare professionals like yourself and we would like to include your opinions. If you qualify for and complete this interview, you will receive an honorarium in exchange for your time and valued feedback. We will now ask you a few questions to determine whether you are qualified for the interview. We want to assure you that your responses will be kept completely confidential.

S1. Which of the following best describes your primary medical specialty?

|  |  |  |
| --- | --- | --- |
| 1 | Primary Care Physician (FP, GP, IM) | **TERMINATE** |
| 2 | Cardiologist |  |
| 3 | Cardiothoracic Surgeon | **TERMINATE** |
| 4 | Electrophysiologist | **TERMINATE** |
| 5 | Interventional Cardiologist |  |
| 6 | Invasive Cardiologist |  |
| 7 | Vascular Surgeon | **TERMINATE** |
| 8 | Other | **TERMINATE** |

*ASK IF S1=2 (Cardiologist)*

S2. Have you been certified by the American Board of Internal Medicine (ABIM) to perform catheter-based cardiovascular procedures, such as angioplasty, stenting, and embolic protection?

|  |  |  |
| --- | --- | --- |
| 1 | Yes |  |
| 2 | No | **TERMINATE** |

S3. Are you board certified or board eligible in your medical specialty?

|  |  |  |
| --- | --- | --- |
| 1 | Board certified |  |
| 2 | Board eligible | **TERMINATE** |
| 3 | Neither | **TERMINATE** |

S4. Which state(s) are you currently licensed to practice in?

|  |  |
| --- | --- |
|  | **TERMINATE IF VT, DC, ME, MN, AND/OR WV** |

S5. How many years have you been qualified in your medical specialty?

|  |  |
| --- | --- |
| # of years | **IF <3 OR >25**  **TERMINATE** |

S6. What percent of your professional time is spent in direct patient care (as opposed to research, teaching, or other pursuits)?

|  |  |
| --- | --- |
| % of professional time | **if <70%, then TERMINATE** |

S7. Which of the following best describes your practice setting?

|  |  |  |
| --- | --- | --- |
| 1 | Major academic center hospital | **CLASSIFY AS “ACADEMIC”** |
| 2 | Major academic center group practice |
| 3 | University teaching hospital |
| 4 | Community teaching hospital | **CLASSIFY AS “COMMUNITY”** |
| 5 | Community hospital (non-teaching) |
| 6 | Group practice |
| 7 | Solo practice |
| 8 | Government-owned (e.g., VA, DoD, State, etc.) | **TERMINATE** |
| 9 | Other (specify) | **OTHER** |
| **RECRUIT A MIX OF COMMUNITY AND ACADEMIC** | | |

S8. How many of the following procedures have you conducted in the past 12 months?

|  |  |  |
| --- | --- | --- |
| *RANDOMIZE* | | **# of Procedures** |
| 1 | Catheter RF Ablation for Atrial Fibrillation |  |
| 2 | Transcatheter Left Atrial Appendage (LAA) Closure |  |
| 3 | Patent Foramen Ovale (PFO) Closure | **TERMINATE IF LESS THAN 5** |
| 4 | Percutaneous Coronary Intervention (PCI) |  |
| 5 | Atrial Septal Defect (ASD) Closure |  |

hS8. PFO PROCEDURE VOLUME (hidden)

|  |  |  |
| --- | --- | --- |
| 1 | Low | *S8r3=5-9* |
| 2 | Moderate | *S8r3=10-15* |
| 3 | High | *S8r3=16+* |

S9. What proportion of your Patent Foramen Ovale (PFO) Closure patients suffer from the following conditions?

*Your response does NOT have to sum to 100%.*

|  |  |  |
| --- | --- | --- |
| *RANDOMIZE* | | **% of PFO Closure Patients** |
| 1 | Cryptogenic Stroke Only | *[RANGE 0-100]* |
| 2 | Migraines Only | *[RANGE 0-100]* |
| 3 | Both Cryptogenic Strokes & Migraines | *[RANGE 0-100]* |
| 5 | Deep Vein Thrombosis | *[RANGE 0-100]* |
| 6 | Hypertension | *[RANGE 0-100]* |
| 7 | Atrial Fibrillation | *[RANGE 0-100]* |
| 8 | Pulmonary Embolism | *[RANGE 0-100]* |
| **TERMINATE IF S9r1 AND S9r3=0** | | |

S10. What is your level of familiarity with each of the following devices for PFO closures?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *RANDOMIZE* | | **Have Never Heard Of Device**  **1** | **Have Heard Of It, But Not Familiar With Device / Device Information**  **2** | **Somewhat Familiar With Device / Device Information**  **3** | **Very Knowledgeable and Familiar With Device / Device Information**  **4** |
| 1 | Abbott **Amplatzer** PFO Occluder |  |  |  |  |
| 2 | Gore **Cardioform** Septal Occluder |  |  |  |  |
| **TERMINATE IF UNAWARE OF ALL DEVICES (S10r~~1-3~~ 1-2 ALL = 1)** | | | | | |

S11. For the next few questions, we would like to ask you about **PFO closure devices**.

Which of the following best describes your use of each PFO closure device?

*Please select one option per row.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | *HOLD S10 RANDOMIZATION* | **Currently Use Regularly**  **1** | **Currently Use Infrequently**  **2** | **Have Used, But No Longer Use**  **3** | **Have Never Used, But Plan To Try**  **4** | **Have Never Used, And Do NOT Plan To Use**  **5** |
| 1 | Abbott **Amplatzer** PFO Occluder *[SHOW IF AWARE (S10r1<>1)]* |  |  |  |  |  |
| 2 | Gore **Cardioform** Septal Occluder  *[SHOW IF AWARE (S10r2<>1)]* |  |  |  |  |  |
| **TERMINATE IF S11 IF S11r1-2 ALL = 3, 4 or 5 (S11r1 <> 1 or 2 and S11r2 <> 1 or 2)** | | | | | | |

S12. Which of the following best describes your role in PFO closure device selection?

|  |  |
| --- | --- |
| 1 | I am the primary decision maker in deciding which PFO closure device to use |
| 2 | I am somewhat involved in the decision making for which PFO closure device to use, but I am not the primary decision maker |
| 3 | I only recommend specific PFO closure devices to patients potentially undergoing the procedure |
| 4 | I do not have any involvement in the recommendation or decision making for which PFO closure device to use **TERMINATE** |

S13. What proportion of your current PFO closure patients fall into the following age categories?

*Your response must sum to 100%.*

|  |  |  |
| --- | --- | --- |
|  | | **% of PFO Closure Patients** |
| 1 | Under 18 years old | *[RANGE 0-100]* |
| 2 | 18-39 years old | *[RANGE 0-100]* |
| 3 | 40-65 years old | *[RANGE 0-100]* |
| 4 | Over 65 years old | *[RANGE 0-100]* |
|  | **TERMINATE IF ~~S12~~ S13r1>49%** | *DISPLAY SUM.*  *SUM MUST =100%* |

S14. Are you or any member of your immediate family currently employed by a medical device, medical device advertising, or marketing research firm as an employee or consultant? Please do not include any involvement you may have with advisory boards.

|  |  |
| --- | --- |
| 1 | Yes **TERMINATE** |
| 2 | No |

S15. Thank you for answering these questions. Based on your responses, we would like to invite you to participate in our study. The survey will take approximately 30 minutes to complete.

We will not ask you to disclose any information that would identify you, such as your name, telephone, email address, etc.

Are you interested in participating?

|  |  |
| --- | --- |
| 1 | Yes |
| 2 | No **TERMINATE** |

S16. Thank you for your interest in participating in this research study. **Cognitive Consulting** wishes to confirm your interest in participating in this research. This Participant Agreement (“Agreement”) sets forth the terms and conditions of your participation.

1. Research Intent. Any information provided to you is for market research purposes only and is not intended to recommend or promote a therapeutic approach, medical procedure, specific product or class of products, or to be a representation of approved product labeling. You have no obligation to use, purchase, recommend or arrange for the use of any therapeutic approach, medical procedure, or product, based on your participation in this market research. You represent that the facts and information that you provide in the course of your participation are true and accurate.
2. Confidentiality. You agree to keep in confidence for a period of three (3) years from the expiration or termination of this Agreement any confidential information disclosed to you during this discussion. “Confidential Information” includes, but is not limited to, information about the Client (if applicable) or the subject of the research that is either proprietary in nature or is not known to the general public.

Your individual responses and any other information you provide in the context of your participation in this research will be kept confidential and will only be used as described in this document and will not be disclosed to any third party (other than those described in this document) without your approval or unless required by regulation or by court order.

1. Payment. As consideration for the time you are taking to participate in this market research and for your performance of the obligations under this Agreement, we shall pay you the amount that was previously communicated in your invitation email.

By checking “I agree” below, you indicate your acceptance of the terms of this Market Research Participant Agreement.

|  |  |
| --- | --- |
| 1 | I agree |
| 2 | I do not agree **TERMINATE** |

S17. Thank you for agreeing to participate in this market research survey. Please be assured that all of your responses will be kept in strict confidence. The data from the survey will be blinded, and we will ensure that the strictest standards of privacy are maintained with the content of your responses. No identifying information will be collected, and all responses will remain anonymous. As such, please make every effort to be open and honest when responding to the questions. The information you provide in this survey is greatly appreciated and valuable.

S18. We are required to pass on to our client details of adverse events and product technical complaints related to their own products that are raised during the course of market research interviews. Although this is an online market research interview and how you respond will, of course, be treated in confidence, should you raise an adverse event or product technical complaint in an individual or group of individuals, we will need to report this.

If you decide to disclose your personal details in association with any adverse event or product technical complaint report, this information will be disclosed to the commissioning company. In such a situation you may be contacted specifically in relation to that adverse event or product technical complaint. Everything else you contribute during the course of the interview will continue to remain confidential.

Are you happy to proceed with the interview on this basis?

|  |  |
| --- | --- |
| 1 | I would like to proceed and give permission for my contact details to be passed on to the product surveillance department of the company if an adverse event or product technical complaint is mentioned by me during the survey. |
| 2 | I would like to proceed but do not wish for my contact details to be passed on to the product surveillance department of the company if an adverse event or product technical complaint is mentioned by me during the survey. |
| 3 | I don’t want to proceed and wish to end the interview here. **TERMINATE** |

**MAIN QUESTIONNAIRE:**

**SECTION A: PFO BACKGROUND AND PATIENT MANAGEMENT**

To begin, we would like to ask you a few questions about you and your patients that have received a **Patent Foramen Ovale (PFO)** closure procedure.

A1. What is your level of agreement with the following statements?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Strongly Disagree**  **1** | **2** | **3** | **4** | **5** | **6** | **Strongly Agree**  **7** |
| 1 | I actively keep up with the trends and innovation in PFO closure procedures and devices |  |  |  |  |  |  |  |
| 2 | I consider myself to be an early adopter compared to other doctors |  |  |  |  |  |  |  |
| 3 | There are a lot of exciting PFO closure devices that are coming into the market |  |  |  |  |  |  |  |
| 4 | I like doing PFO closure procedures |  |  |  |  |  |  |  |
| 5 | More patients should be referred for this procedure |  |  |  |  |  |  |  |
| 6 | I am satisfied with the device I currently use for PFO closure procedures |  |  |  |  |  |  |  |
| 7 | There are major challenges with the current PFO devices I use today |  |  |  |  |  |  |  |
| 8 | If my patient requests that a specific device be used, I am likely to use that device |  |  |  |  |  |  |  |
| 9 | I am just as likely to use a new product from a small/newer company as a new product from a large/established company |  |  |  |  |  |  |  |
| 10 | Early identification of patients in need of PFO closures is important |  |  |  |  |  |  |  |

*ASK IF ~~A3~~ A1r7=5-7*

A2. What are some of the improvements you would like to see with the devices you are currently using to perform PFO closure procedures today?

*Please be as detailed as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

A3. Using a 7-point scale, where 1=Not at all Impactful and 7=Extremely Impactful, how impactful are each of the following on how you perceive a PFO closure device’s **ease of use**?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Not at all Impactful**  **1** | **2** | **3** | **4** | **5** | **6** | **Extremely Impactful 7** |
| 1 | Tension free positioning assessment |  |  |  |  |  |  |  |
| 2 | Device comes preloaded |  |  |  |  |  |  |  |
| 3 | Intuitive delivery system controls |  |  |  |  |  |  |  |
| 4 | Reliability/consistency in positive experience |  |  |  |  |  |  |  |
| 5 | Over-the-wire deployment |  |  |  |  |  |  |  |
| 6 | Fluoro/echo visibility |  |  |  |  |  |  |  |
| 7 | Short procedure time |  |  |  |  |  |  |  |
| 8 | Ease of choosing the right device size |  |  |  |  |  |  |  |
| 9 | One & done deployment |  |  |  |  |  |  |  |
| 10 | Extra length on the delivery catheter |  |  |  |  |  |  |  |
| 11 | No nickel metal present |  |  |  |  |  |  |  |
| 12 | Need for clinical support in the room |  |  |  |  |  |  |  |

**SECTION B: PFO MARKET AND DEVICE USAGE**

*CURRENT SHARE (BASE CASE)*

B1. Based on the *[INSERT S8r3]* Patent Foramen Ovale (PFO) Closure procedures you have conducted in the past year, what percent of the following devices have you **personally** used for this procedure among your patients?

*Your response must sum to 100%*

|  |  |  |
| --- | --- | --- |
| *HOLD RANDOMIZATION FROM S10. AUTOFILL BLANKS WITH ZEROS IF NOT SHOWN* | | **% of PFO Closure Patients** |
| 1 | Abbott **Amplatzer** PFO Occluder  *[SHOW IF USER (S11r1=1 OR 2)]* | *[RANGE 0-100]* |
| 2 | Gore **Cardioform** Septal Occluder  *[SHOW IF USER (S11r2=1 OR 2)]* | *[RANGE 0-100]* |
| 3 | Other (specify) *[SPECIFY] [ANCHOR]* | *[RANGE 0-100]* |
|  |  | *DISPLAY SUM.*  *SUM MUST =100%* |

*ASK IF B1r2>0*

B2A. What are the primary reasons that you use the **Gore Cardioform Septal Occluder**?

*Please be as detailed as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

*ASK IF B1r1>0*

B2B. What are the primary reasons that you use the **Abbott Amplatzer PFO Occluder**?

*Please be as detailed as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

*ASK IF B1r2=0 AND S11r2=1, ~~OR~~ 2, 3, 4, OR 5*

B3A. What are the primary reasons that you do NOT use the **Gore Cardioform Septal Occluder**?

*Please be as detailed as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

*ASK IF B1~~r2~~ r1=0 AND S11r1=1, ~~OR~~ 2, 3, 4, OR 5*

B3B. What are the primary reasons that you do NOT use the **Abbott Amplatzer PFO Occluder**?

*Please be as detailed as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

B4. Using a 7-point scale, where 1=Not At All Satisfied and 7=Extremely Satisfied, what is your level of satisfaction with the following PFO closure devices?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | **Not At All Satisfied**  **1** | **2** | **3** | **4** | **5** | **6** | **Extremely Satisfied**  **7** |
| 1 | Abbott **Amplatzer** PFO Occluder  *[SHOW IF USER (~~S11r1=1 OR 2~~ B1r1>0)]* |  |  |  |  |  |  |  |
| 2 | Gore **Cardioform** Septal Occluder  *[SHOW IF USER (~~S11r2=1 OR 2~~ B1r2>0)]* |  |  |  |  |  |  |  |

*ASK IF B4R2=1-3 (DISSATISFIED WITH GORE CARDIOFORM SEPTAL OCCLUDER)*

B5A. Why are you unsatisfied with **Gore Cardioform Septal Occluder**?

*Please be as specific as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

*ASK IF B4R1=1-3 (DISSATISFIED WITH ABBOTT AMPLATZER PFO OCCLUDER)*

B5B. Why are you unsatisfied with **Abbott Amplatzer PFO Occluder**?

*Please be as specific as possible.*

|  |
| --- |
| *OPEN END – FORCE MIN OF 4 CHARACTERS* |

B6. Based on your clinical experience with PFO closure procedures, what percent of the time do you experience the following with each device you use in your clinical practice?

*Please provide your best estimates. Your response does NOT have to sum to 100%.*

|  |  |  |  |
| --- | --- | --- | --- |
| *RANDOMIZE* | | **Abbott Amplatzer PFO Occluder**  *[SHOW IF USER (~~S11r3>0 r1=1 or 2~~ B1r1>0)]* | **Gore Cardioform Septal Occluder**  *[SHOW IF USER (~~S11r2>0=1 or 2~~ B1r2>0)]* |
| 1 | Closure Rate @ 6 months | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 2 | Embolization (Device Dislodges) | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 3 | Atrial Arrhythmia (any) | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 4 | Device-Related Thrombus (DRT) | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 5 | Procedural/Technical Success | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 6 | Nickel Sensitivity | *[RANGE 0-100]* | *[RANGE 0-100]* |
| 7 | Device-Related Erosion | *[RANGE 0-100]* | *[RANGE 0-100]* |

*ASK IF ABBOTT USER (B1~~r2~~ r1>0). RANDOMIZE ORDER THAT B7 AND B8 ARE SHOWN.*

B7. Using a 7-point scale, where 1=Very Poor and 7=Very Well, how does the **Abbott Amplatzer PFO Occluder** perform in the following areas?

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Very Poor**  **1** | **2** | **3** | **4** | **5** | **6** | **Very Well**  **7** | **Unsure**  **99** |
| 1 | On-table Closure Rate |  |  |  |  |  |  |  |  |
| 2 | Closure Rate @ 6 months |  |  |  |  |  |  |  |  |
| 3 | Embolization (Device Dislodges) |  |  |  |  |  |  |  |  |
| 4 | Any atrial arrhythmia post implant |  |  |  |  |  |  |  |  |
| 5 | Device Frame-Related post implant cardiac injury rate (Erosion or Perforation) |  |  |  |  |  |  |  |  |
| 6 | Time to complete endothelialization |  |  |  |  |  |  |  |  |
| 7 | Device-Related Thrombus (DRT) |  |  |  |  |  |  |  |  |
| 8 | Crossability (transseptal crossing post-implant) |  |  |  |  |  |  |  |  |
| 9 | Ease of use |  |  |  |  |  |  |  |  |
| 10 | PFO size treatment range |  |  |  |  |  |  |  |  |
| 11 | Device preparation time |  |  |  |  |  |  |  |  |
| 12 | Consistent device procedural time |  |  |  |  |  |  |  |  |

*ASK IF GORE USER (B1~~r1~~ r2>0). RANDOMIZE ORDER THAT B7 AND B8 ARE SHOWN.*

B8. Using a 7-point scale, where 1=Very Poor and 7=Very Well, how does the **Gore Cardioform Septal Occluder** perform in the following areas?

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Very Poor**  **1** | **2** | **3** | **4** | **5** | **6** | **Very Well**  **7** | **Unsure**  **99** |
| 1 | On-table Closure Rate |  |  |  |  |  |  |  |  |
| 2 | Closure Rate @ 6 months |  |  |  |  |  |  |  |  |
| 3 | Embolization (Device Dislodges) |  |  |  |  |  |  |  |  |
| 4 | Any atrial arrhythmia post implant |  |  |  |  |  |  |  |  |
| 5 | Device Frame-Related post implant cardiac injury rate (Erosion or Perforation) |  |  |  |  |  |  |  |  |
| 6 | Time to complete endothelialization |  |  |  |  |  |  |  |  |
| 7 | Device-Related Thrombus (DRT) |  |  |  |  |  |  |  |  |
| 8 | Crossability (transseptal crossing post-implant) |  |  |  |  |  |  |  |  |
| 9 | Ease of use |  |  |  |  |  |  |  |  |
| 10 | PFO size treatment range |  |  |  |  |  |  |  |  |
| 11 | Device preparation time |  |  |  |  |  |  |  |  |
| 12 | Consistent device procedural time |  |  |  |  |  |  |  |  |

*ASK IF ABBOT USER (B1~~r2~~ r1>0). RANDOMIZE ORDER THAT B9 AND B10 ARE SHOWN.*

B9. Using a 7-point scale, where 1=Not at all Satisfied to Use and 7=Very Satisfied, how satisfied are you with the **Abbott Amplatzer PFO Occluder** in each of the following areas related to the ease of use of the device?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Not at all Satisfied**  **1** | **2** | **3** | **4** | **5** | **6** | **Very Satisfied**  **7** |
| 1 | Tension free positioning assessment |  |  |  |  |  |  |  |
| 2 | Device comes preloaded |  |  |  |  |  |  |  |
| 3 | Intuitive delivery system controls |  |  |  |  |  |  |  |
| 4 | Reliability/consistency in positive experience |  |  |  |  |  |  |  |
| 5 | Over-the-wire deployment |  |  |  |  |  |  |  |
| 6 | Fluoro/echo visibility |  |  |  |  |  |  |  |
| 7 | Short procedure time |  |  |  |  |  |  |  |
| 8 | Ease of choosing the right device size |  |  |  |  |  |  |  |
| 9 | One & done deployment |  |  |  |  |  |  |  |
| 10 | Extra length on the delivery catheter |  |  |  |  |  |  |  |
| 11 | No nickel metal present |  |  |  |  |  |  |  |
| 12 | Need for clinical support in the room |  |  |  |  |  |  |  |

*ASK IF GORE USER (B1~~r1~~ r2>0). RANDOMIZE ORDER THAT B9 AND B10 ARE SHOWN.*

B10. Using a 7-point scale, where 1=Not at all Satisfied to Use and 7=Very Satisfied, how satisfied are you with the **Gore Cardioform Septal Occluder** in each of the following areas related to the ease of use of the device?

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *RANDOMIZE* | **Not at all Satisfied**  **1** | **2** | **3** | **4** | **5** | **6** | **Very Satisfied**  **7** |
| 1 | Tension free positioning assessment |  |  |  |  |  |  |  |
| 2 | Device comes preloaded |  |  |  |  |  |  |  |
| 3 | Intuitive delivery system controls |  |  |  |  |  |  |  |
| 4 | Reliability/consistency in positive experience |  |  |  |  |  |  |  |
| 5 | Over-the-wire deployment |  |  |  |  |  |  |  |
| 6 | Fluoro/echo visibility |  |  |  |  |  |  |  |
| 7 | Short procedure time |  |  |  |  |  |  |  |
| 8 | Ease of choosing the right device size |  |  |  |  |  |  |  |
| 9 | One & done deployment |  |  |  |  |  |  |  |
| 10 | Extra length on the delivery catheter |  |  |  |  |  |  |  |
| 11 | No nickel metal present |  |  |  |  |  |  |  |
| 12 | Need for clinical support in the room |  |  |  |  |  |  |  |

**SECTION C: HYBRID CONJOINT EXERCISE**

You will now see a series of screens. Each will show you different device descriptions for **two** **PFO closure devices**. You will be asked which option you would use and for what percent of your patients you would use that device compared to current devices on the market. The device description will change from screen to screen.

As you review the PFO closure device descriptions, please note that these devices are hypothetical. Therefore, when answering the questions, please react to the device descriptions outlined on each screen assuming that they will be available, even if you believe the device(s) may not be achievable.

There will be xx screens for you to review.

Please click “NEXT” to begin the exercise.

*INSERT DEVICE SCENARIOS.*

*PROGRAMMING NOTE: PLEASE SHOW THE FOLLOWING TEXT ABOVE THE DEVICE PROFILES OF THE CBC CONJOINT.*

Please assume that the following devices will be available within your hospital/health system without restrictions and with reasonable out-of-pocket costs.

Screen 1 of xx

*PROGRAMMING NOTE: PLEASE SHOW THE FOLLOWING TEXT BELOW THE DEVICE PROFILES OF THE CBC CONJOINT. ~~SHOW PART A ON ONE SCREEN AND PART B ON THE NEXT SCREEN.~~ ALWAYS SHOW THE PROFILES OF THE CBC CONJOINT ABOVE.*

C1. Which of these options would you be most likely to use in the future?

|  |  |
| --- | --- |
| 1 | Option A |
| 2 | Option B |
| 3 | Neither |

*SHOW C2 IF C1=1 OR 2. IF C1=3, AUTOFILL C2~~r6~~r4c2 AND C2~~r7~~r5c2 AS 0 AND ~~B4c2~~ C2r1c2 - C2r3c2 RESPONSES WITH COLUMN 1 RESPONSES (FROM ~~B4~~ B1).*

C2. Consider your PFO closure patients. If [*IF C1=1:* **“Option A”** *IF C1=2:* **“Option B”**] were to become available in the future, please indicate how your PFO closure device usage would change, if at all, by distributing the proportion of patients across the list of devices.

*Please note that we have included your original allocations as a reference during this exercise. Your response must equal to 100%.*

*INSERT DEVICE SCENARIOS RESPONSES.*

**-----------------------------APPLY COMPUTER-BASED CBC EXERCISE------------------------**

|  |  |  |  |
| --- | --- | --- | --- |
| *Autofill blanks with zeros if column total meets minimum requirement.* | | **PFO Closure Patients** | |
| **Original** | **% with New Options** |
| 1 | Abbott **Amplatzer** PFO Occluder | *[INSERT B1r1]* |  |
| 2 | Gore **Cardioform** Septal Occluder | *[INSERT B1r2]* |  |
| 3 | *[INSERT OTHER FROM ~~S10~~ B1r3]*  *[SHOW IF B1r3>0]* | *[INSERT B1~~r4~~ r3]* |  |
| 4 | **Option A** *[ONLY SHOW IF CODE 1 SELECTED IN PART A. OTHERWISE, AUTOFILL AS 0%]* |  |  |
| 5 | **Option B** *[ONLY SHOW IF CODE 2 SELECTED IN PART A. OTHERWISE, AUTOFILL AS 0%]* |  |  |
|  |  |  | *DISPLAY SUM. SUM MUST=100%* |

**SECTION D: MANUFACTURER PERCEPTIONS**

D1. How likely would you be to recommend the following cardiac device manufacturers to a friend or colleague?

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | *Randomize* | **Not At All Likely to Recommend**  **0** | **1** | **2** | **2** | **4** | **5** | **6** | **7** | **8** | **9** | **Highly Likely to Recommend**  **10** | **I Don’t Know this Company** |
| 1 | Abbott Laboratories |  |  |  |  |  |  |  |  |  |  |  |  |
| 2 | Gore Medical |  |  |  |  |  |  |  |  |  |  |  |  |
| 3 | Occlutech |  |  |  |  |  |  |  |  |  |  |  |  |
| 4 | Boston Scientific |  |  |  |  |  |  |  |  |  |  |  |  |
| 5 | Edwards Lifesciences |  |  |  |  |  |  |  |  |  |  |  |  |
| 8 | Medtronic |  |  |  |  |  |  |  |  |  |  |  |  |
| 9 | CARAG |  |  |  |  |  |  |  |  |  |  |  |  |
| 10 | Cardinal Health/Cordis |  |  |  |  |  |  |  |  |  |  |  |  |

**SECTION E: DEMOGRAPHICS**

E1. Do you participate in a CMS (Centers for Medicare and Medicaid Services) Quality Payment Program?

|  |  |
| --- | --- |
| 1 | Yes |
| 2 | No |
| 3 | Unsure |

*ASK IF E1=1*

E2. Which CMS (Centers for Medicare and Medicaid Services) Quality Payment Program do you participate in?

|  |  |
| --- | --- |
| 1 | MIPS (Merit Based Incentive Payment System) |
| 2 | APMS (Advanced Alternative Payment Models) |
| 3 | Other (specify) |
| 99 | Don’t know |

E3. How would you describe the area in which you practice most of the time?

|  |  |
| --- | --- |
| 1 | Urban (within city) |
| 2 | Suburban (residential area on the outskirts of a city) |
| 3 | Rural (settled areas outside towns and cities) |

E4. What is your age?

|  |  |
| --- | --- |
| 1 | Less than 30 years |
| 2 | 30-39 years old |
| 3 | 40-49 years old |
| 4 | 50-59 years old |
| 5 | 60-69 years old |
| 6 | 70 or older |
| 98 | Prefer not to answer |

**~ END OF QUESTIONNAIRE ~**