




BUILDING A MEDICAL DEVICE

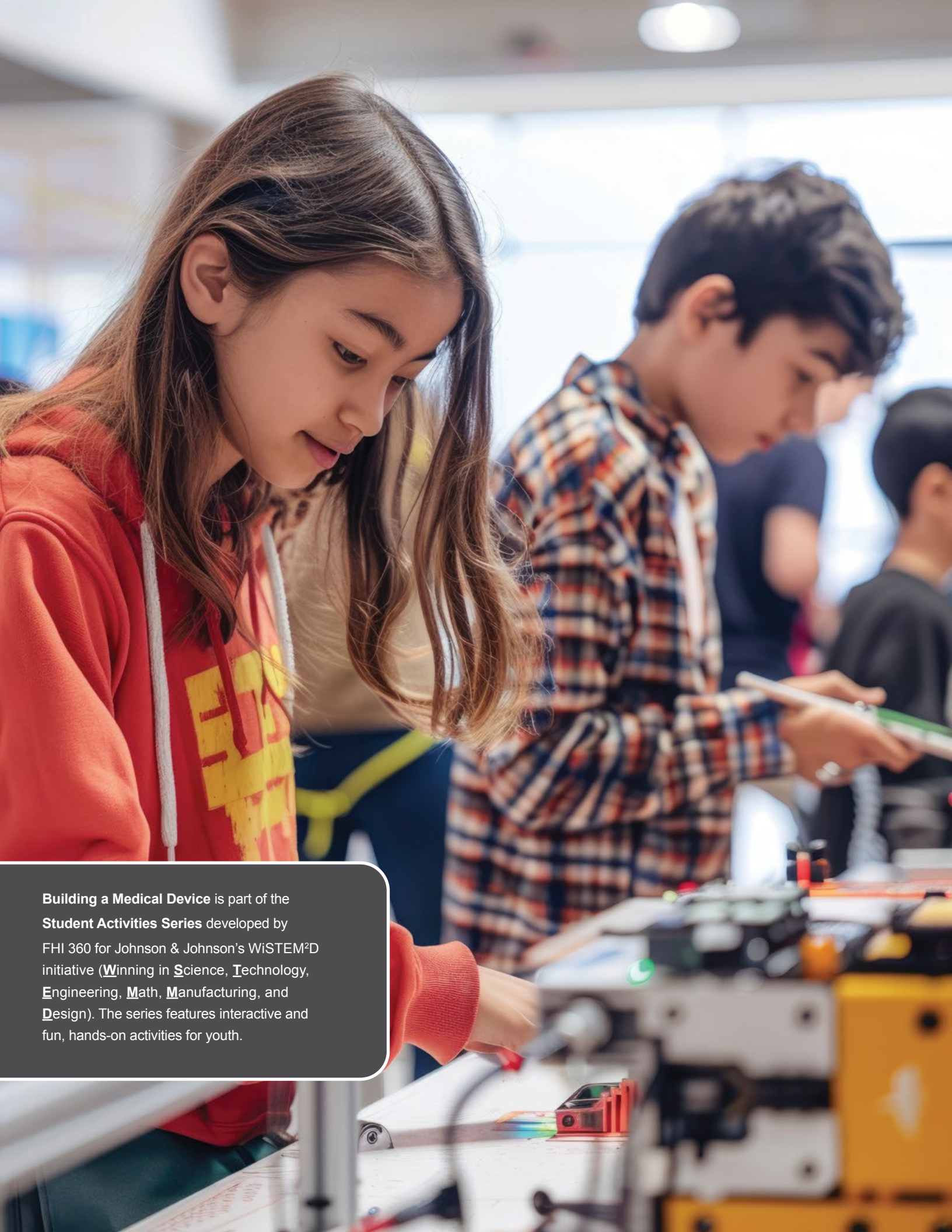
STEM²D Topics:

Design

Engineering

Target Population:

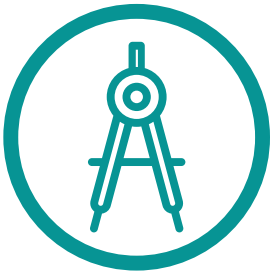
Students, ages 12–18



Building a Medical Device is part of the **Student Activities Series** developed by FHI 360 for Johnson & Johnson's WiSTEM^{2}D initiative (**W**inning in **S**cience, **T**echnology, **E**ngineering, **M**ath, **M**anufacturing, and **D**esign). The series features interactive and fun, hands-on activities for youth.

BUILDING A MEDICAL DEVICE

STEM²D Topics: Design, Engineering
Target population: Students, ages 12–18



ACTIVITY DESCRIPTION

In this team-based, hands-on activity, students will design, build, and test a medical device that meets a customer's needs.

ESTIMATED TIME

This session typically takes **150 minutes** to complete and should be conducted in **one** session.

STUDENT DISCOVERIES

Students will:

- Participate in a team-based learning experience.
- Build important STEM²D—Science, Technology, Engineering, Math, Manufacturing, and Design—skills, such as creative thinking, critical thinking, problem solving, decision making, and teamwork.
- Realize that STEM²D offers diverse and exciting career opportunities.
- Have fun experiencing STEM²D.

GETTING READY

Materials:

- Pre-Activity Checklist
- Tell My Story Form
- Challenge Scoring Sheet, *1 per team for the Judge*
- Computer with projector, speaker, and Internet access
- PowerPoint: Building a Medical Device
- Video: Laparoscopic Surgery: How it is done (SingJealth Nursing Conference, 2017) https://www.youtube.com/watch?v=gwocfmcKebc

STEM²D Skills

- Collaboration
- Communication
- Critical Thinking
- Decision Making
- Problem Solving
- Teamwork
- Testing

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- Student Handout: Building a Medical Device Challenge, *1 per student*
- Student Handout: Cost of Goods Form, *1 per team*
- 18 mm trocar (a surgical instrument with a three-sided cutting point enclosed in a tube)
- Timing device (mobile phone timer or stopwatch)
- 5-gallon container filled with water
- 12 small balloons filled with water
- Rulers (with mm and cm), *1 per team and 1 for the Judge*
- Medical Device Challenge Materials:
  - 10–15 wooden skewers
  - 50 pipe cleaners
  - 1 bag of cotton balls (50–100 count)
  - 50 plastic straws
  - 50 plastic beads (size: 8 mm)
  - 50 wooden beads (size: 8 mm)
  - 75 rubber bands
  - 75 paper clips
  - 6 bottles of glue (e.g., Elmer's)
  - 12 glue sticks
  - 3 rolls of electrical tape
  - 25 white labels (maximum size 1x3 inches)
  - 25 color labels (maximum size 1x3 inches)
  - 50 small stickers (circles and stars)


PRE-ACTIVITY CHECKLIST:

BUILDING A MEDICAL DEVICE

DID YOU...

Estimated Cost:

Activity leaders can expect to incur less than $50.00 in materials costs when completing this activity with up to 30 students organized into teams of five students. Materials above are based on 30 students.

Activity Leader Preparation

1. **Read Spark WiSTEM²D**. This is essential reading for all volunteers interested in working with youth. It defines the STEM²D principles and philosophy and provides research-based strategies and tips for engaging and interacting with students. Download at www.STEM2D.org.

2. Review the **Pre-Activity Checklist** (at the end of this document) for details and specific steps for planning, preparing, and implementing this activity.
3. See the **STEM²D Student Activities Overview** for additional information.
4. Secure two volunteers to assist you in the following roles: Supplier and Judge; additional volunteers are recommended and should be assigned to specific teams.
5. Set up a "Materials Store"—a table or area of the room where teams can purchase the challenge materials from the Supplier.

STEP-BY-STEP INSTRUCTIONS: BUILDING A MEDICAL DEVICE

1. **Welcome and Introductions (5 minutes)**
   - Welcome the students.
   - Introduce yourself by saying your name, title, and your organization/company.
   - Share that students will be learning about STEM²D careers and will be applying STEM²D skills during the session.
   - **(What is STEM²D? Slide)** Explain that **STEM²D** refers to: Science, Technology, Engineering, Math, Manufacturing, and Design.
   - Ask students and other volunteers to introduce themselves and state their favorite area of STEM²D and why it is their favorite.
   - **(Today's Plan Slide)** Review the agenda. Explain that today students will design, build, and test a medical device that meets a customer's needs.

2. **Career Awareness: Design and Engineering in the World of Work (10 minutes)**
   - **(STEM²D in the World of Work Slide)** Initiate an opening discussion and brainstorming activity. Consider asking:
     - How do you think design and engineering are used every day in the workplace?
     - What kinds of careers do you think people with an interest, aptitude for, or degree in design and engineering would have?

KEY WORDS

- **Atraumatic**
- **Concept**
- **Engineering**
- **Laparoscopic**
- **Mass**
- **Pilot**
- **Process**
- **Profitable**
- **Prototype**
- **Reliability**
- **Sterilization**
- **Sustained**
- **Trocar**

TIPS ON STARTING CONVERSATIONS

- What area of STEM²D is your favorite?
- Why did you choose that area of STEM²D as your favorite?
- What would your dream job be?
- Where do you see yourself in five to ten years?

TIPS ABOUT STEM²D CAREERS

Share with students that there are many different kinds of careers related to STEM²D. Possible STEM²D careers related to this activity:

- Biomedical Engineer
- Industrial Design Engineer
- Manufacturing Engineer
- Marketing and Sales
- Medical Affairs
- Packaging Engineer
- Production Engineer
- Quality & Testing Analyst/ Engineer/Scientist
- Sterilization Scientist

- **(My Story Slides)** Talk about your educational and career path. Use the Tell My Story form as the basis for your remarks. Be prepared to describe your job or a typical day, and provide information about your background including:
  - When/why you developed an interest in design and/or engineering
  - The classes/courses you took in secondary school
  - Your post-secondary path, including the institution you attended and your degree. *If you switched disciplines, make sure you explain why to the students.*
  - What your current position entails. *Be sure to include how you use design and/or engineering and what you do on a typical work day.*
- Weave in facts about design, engineering, and other STEM²D careers:
  - Tell the students that your career is only one of the many careers available in the STEM²D disciplines.
  - Explain that STEM²D careers are high-demand, high-growth careers and are predicted to remain in demand over the next ten years.
  - Share a few Johnson & Johnson job titles and careers that may align with this activity (e.g., Biomedical Engineer, Design Engineer, Quality & Testing Analyst, Marketing and Sales).

3. **Content Presentation (25 minutes)**
   - **(What is Engineering? Slide)** Explain: **Engineering** is the application of scientific, economic, social, and practical knowledge in order to design, build, maintain, and improve structures, machines, devices, systems, materials, and processes. Indicate that the discipline of engineering is extremely broad and encompasses a range of specialized fields, each with an emphasis on a particular area of technology and type of application.
   - **(Background of Surgery Slide)** State that engineering has led to significant improvements in surgery. For example:
     - Surgeons used to make large incisions to access muscles, organs, bones, etc.

- Today, surgeons are able to access these areas through three to four small incisions (laparoscopy).
- Recently, robotic systems have been introduced to access the same areas with a single incision or one small hole, achieving the same results.

- **(Laparoscopic Surgery Slide)** Explain: Laparoscopy is a surgical procedure in which a fiber-optic instrument is inserted through the abdomen (a single hole or three to four small incisions) to view the organs and perform a procedure. State that there are many benefits of laparoscopy compared to traditional surgery. Review the benefits listed on the slide with the students.
- **(Examples of Laparoscopic Devices Sold by J&J Slide)** Say: Johnson & Johnson Medical (ETHICON), a division of Johnson & Johnson, develops laparoscopic devices and has contributed to many advances in the field of laparoscopy, such as vessel-sealing devices, cutting devices, stapling devices, ligation devices, and many more!
- **(Trocar Slide)** Tell students: One laparoscopic device is a trocar; a trocar is a pen-shaped medical device used in surgery. It has a sharp, three-sided (triangular) cutting point at one end. It is attached to a hallow tube (known as a cannula or sleeve) and used to create an opening in the body and provide an access point during surgery. It is minimally invasive, which is extremely beneficial to the patient, as seen in the image.
- **(Video Slide)** If time permits, click on the links in the PowerPoint to show the 2-minute video, which simulates a laparoscopic surgery.
- **(Engineering a New Product Slide)** Explain that there are many different engineering processes. Review the three-phase process, which will be used in today's activity:
  1. Phase 1: Design. Key steps during this phase include:
     - *Concept Design.* This first step is critical; it includes analyzing and identifying what the customer wants or needs and creating a concept (an idea or general plan) based on those inputs.
     - *Product Planning.* This step lays out the reason the business should pursue the concept and provides a

TIPS FOR MAKING CONNECTIONS

Encourage students to:

- Ask questions if they don't understand
- Summarize what they have learned
- Explain their thinking process aloud

plan for how the concept will be achieved (what the design looks like, who will provide the parts, what the critical wants/needs are, and how long it will take to develop).

2. Phase 2: Development. Steps include:
    - *Prototype Building.* This step involves creating the first fully functioning prototype (model) of the proposed product to showcase. This original prototype is not likely to be manufactured; the design is apt to change significantly along the way, based on testing in a controlled environment. Testing is conducted to see if the prototype produces the desired outcome. Redesign and rebuilding occur to perfect the working prototype.
    - *Pilot Production.* This step involves piloting or testing your manufacturing process to determine if you can create your final design consistently. During this phase, packaging design and integration with production is also taken into account.
3. Phase 3: Production. Steps include:
    - *Mass Production.* This step begins when you have demonstrated that you can create your final design consistently using the manufacturing process developed and can begin producing the product to sell to customers.
    - *Sustained Support.* This step begins after you launch the product to customers and does not end until the product is no longer sold. Activities can include technical support, customized marketing and sales, warranty and complaint support, and design improvements. (Define **sustained:** prolonged for an extended period or without interruption.)

- Indicate that throughout the engineering process—in every phase and in all steps—design review occurs. The entire team continuously evaluates the capability and performance of the design to meet requirements; if concerns or shortcomings are identified, the design is modified.

- **(It Takes a Village Slide)** Explain: Many jobs are required to launch a new product—especially in the health or medical sectors. These jobs include:
  - Biomedical Engineers: Specialize in the development and design of medical products
  - Industrial Design/Design Engineers: Design products
  - Labeling Specialists: Write instructions for use
  - Marketing and Sales Representatives: Promote or sell the product
  - Manufacturing Engineers: Establish the production line
  - Procurement Managers / Supply Chain Specialists: Obtain raw materials and determine logistics for bring the manufacturing product to the customer
  - Medical Affairs staff: Provide medical expertise regarding procedures
  - Packaging Engineers: Design product packaging
  - Pre-Clinical Scientists: Test products to ensure they work properly
  - Quality & Testing Analysts: Responsible for product functionality, reliability, and patient safety
  - Regulatory Affairs staff: Work with Food and Drug Administration (FDA) to approve devices
  - Sterilization Scientists: Work on **sterilization** (the process of making something free from bacteria or other living microorganisms) processes to ensure devices are sterile when used
- Note any other relevant Johnson & Johnson roles.
- **(Questions? Slide)** Ask the students if they have any questions about engineering, the engineering process, or various careers associated with product development. Answer questions posed by the students.

4. **Learning Activity: Building a Medical Device (60 minutes)**
   Divide the 65-minute learning activity into two sections: 1) an overview (10 minutes) and 2) the team challenge (50 minutes). Initiate the overview:
   - **(Build a Medical Device Challenge Slide)** Break the students into teams of five and have them sit together for the remainder

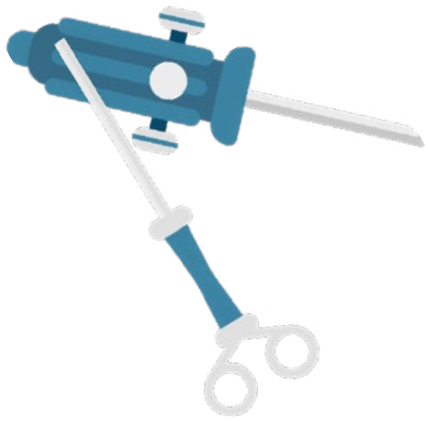
TIPS FOR WORKING WITH STUDENTS

- Ask open-ended questions to encourage student reflection and discussion. For example:
  - How did you decide what materials to use?
  - What factors determined the design of your medical device?
  - What was most challenging about building the medical device?
  - Did you make changes to your design and why?
  - How did you determine who would assume each role?
  - What have you learned so far in this process?
- Help students stay on track with time during the group challenge.
- Encourage all students to participate in the different stages of the challenge.
- Move around the learning space and provide support when necessary.

of the session. (If a team does not have five members, someone may need to play dual roles.) Distribute the student handouts and a ruler to each team.

- **(Making Engineering Real Slide)** Explain: You will work as a team of five people to design a medical device prototype that meets customer needs, safety standards, and business constraints.
- **(Challenge Tasks Slide)** Review the main tasks:
  - Work as a team. Each member will assume a specific role.
  - Design a prototype of a medical device that meets all product requirements (customer needs, safety standards, and business constraints).
  - Build the prototype using only the materials available for purchase.
  - Determine the device name and product selling points.
  - Present the prototype.
  - Teams have 50 minutes to complete all tasks and three minutes to present to the judge.
- Introduce the Judge (the volunteer assigned to this role). Indicate that the judge will hear the presentations and determine if each team meets the customer, safety standards, and business requirements.
- **(Challenge Roles and Responsibilities Slide)** State: Each team member will have a role in the creation of the prototype:
  - Design Engineer: Develops a concept that meets all product requirements
  - Procurement Manager: Purchases and tracks all materials used and costs
  - Manufacturing Engineer: Builds the prototype and makes recommended modifications
  - Marketing and Sales Manager: Develops requirements for the product and means to sell it to the customer
  - Quality / Testing Analyst: Ensures product functionality and alignment with safety standards
- Tell teams that the student handout provides additional details about each role. Give teams one minute to determine each member's role.

- **(Product Requirements: Voice of the Customer Slide)** Reconvene the large group. Remind teams that the prototype must meet the needs of the customers. Explain: Your customers (a panel of surgeons) have specific needs:
  - Surgeon Dr. Smith: “I want to be able to push tissue out of my surgical sight.”
  - Surgeon Dr. Anderson: “I am left-handed, and I want it to be easy to use.”
  - Surgeon Dr. Wu: “I want it to be a natural extension of my hand.”
  - Surgeon Dr. Johnson: “I need to be able to see the tip of the device when it’s in the tissue.”
- **(Product Requirements: Safety Standards and Business Requirements Slide)** State that there are other product requirements:
  - Safety standards. The devise must:
    - Be atraumatic: it can’t do any damage to the tissue
    - Fit through an 18 mm trocar
    - Be long enough to extend through a 15 cm port
    - Stay assembled when immersed in water for one minute
  - Business constraints/requirements. The device must:
    - Have a name and detailed designs for patent application
    - Be cost efficient: the sales price is $20.00, maximum
    - Be **profitable** (an activity yielding profit or financial gain): keep the Cost of Goods (COGs) to less than 20% of the sales price ($16.00, maximum)
    - Include a Tracking Sticker
- **(Can You Turn This Into This? Slide)** Explain: Every product starts out as a concept (an idea or general plan) before to being sold to a customer. In many instances the original concept is developed into an initial prototype using basic materials to help visualize what the final design may look like.
- **(Materials Slide)** State: Teams can use a variety of supplies to build their devices; each supply is associated with a dollar value. As indicated by the business requirements, the device will sell for $20, and the total cost of the materials must be 20% less



than the sales price to be profitable ($16.00, maximum).

The costs of the supplies are as follows:

- Wood skewer = $1.00
- Pipe cleaner = $0.75
- Cotton ball = $0.75
- Plastic straw = $0.65
- Plastic bead = $0.65
- Wood bead = $0.50
- Rubber band = $0.50
- Paper clip = $0.50
- Electrical tape (6-inch length) = $0.25
- Glue = $0.20
- Glue stick = $0.20
- Color label = $0.20
- White label $0.10
- Star sticker = $0.10
- Circle sticker = $0.05

- Point out the materials store and introduce the Supplier (the volunteer assigned to distribute the supplies). State that each Procurement Manager will purchase the materials from the materials store and record the cost of all materials purchased and used on the Cost of Goods form; any unused materials can be returned to the materials store. Remember that the cost of materials must be less than 20% of the sales price.
- Remind teams that they have 50 minutes to design, build, and test their design, as well as prepare the presentation.
- Point to the designated performance testing area. Emphasize that teams can test their prototypes at any time to ensure they meet the challenge requirements.
- Encourage teams to review the student handout for additional instructions about the challenge.
- **(Questions? Slide)** Ask the students if they have any questions about the challenge before getting started. Answer questions posed by the students.
- **(Building a Medical Device Challenge Slide)** Instruct teams to begin the 50-minute challenge.
- While teams are working on the challenge, circulate around the room asking students questions about their designs. While you

may be tempted to give suggestions for improvement, hold on to the suggestions until the reflection period of the activity to give teams the opportunity to work through the product design process.

5. **Performance Testing (35 minutes)**

   After 50 minutes, reconvene the large group. Indicate that it is time for each team to test and present its device to the large group.

   - **(Scoring Slide)** Re-introduce the Judge (the volunteer assigned to this task). Inform the teams that the Judge will verify each team's cost of materials and score the prototype based on the product requirements. Refer to the checklist on the slide. Provide the Judge with one Challenge Scoring Sheet for each team.
   - **(Team Presentations and Performance Testing Slide)** Remind students that each team's Marketing Manager will make the three-minute presentation. Indicate that testing will take place immediately after the presentation.
   - Randomly choose one team to come to the front of the room with their device. Ask the Marketing Manager to start the presentation.
   - Once the presentation is complete, ask the team's Procurement Manager to state the cost of materials used to build the device. Confirm that the total cost of materials is no more than $16.00 (20% less than the maximum device cost of $20.00).
   - With the team's Quality / Testing Analyst, test the device:
     1. Place the device through the 18 mm trocar.
     2. Measure the device using the metric ruler to verify the device is longer than 15 cm.
     3. Use the device to push a water balloon a distance of 6 inches inside the water-filled bin.
     4. Fully submerge the device in the water-filled bin for one minute. (Ask the Judge to use the timer.)
   - Have the Judge total the number of "YES" answers on the team's score sheet.

- Repeat the presentation and testing process with each team until all teams have had a chance to present and test their devices.
- Announce the teams that were the most successful (based on the Judge's scores).
- Remind students that products are often redesigned or rebuilt as they go through the engineering development process.
- **(What Did We Learn? Slide)** Ask students the following questions:
    - What was the most critical decision your team made during the design process?
    - What did you learn about working in a team?
    - What was the most critical decision your team made during the manufacturing process?
    - What was difficult about designing and building your medical device?
    - What would you change about your design if you were to do it again?

6. **Student Reflection (15 minutes)**
    - **(Reflection Slide)** Ask students to relect on the activity. Have them spend a few minutes thinking about the listed questions and then ask for students to share their thoughts.
        - What did you learn about engineering?
        - How do you think this activity relates to a career in engineering and/or working at Johnson & Johnson?
        - Can you see yourself as a STEM^{2}D professional? In what role? Why or why not?
        - What would you need to do to make that happen?
        - What is one thing you learned that you did not know coming into today?

Extended Learning

Here are a few ways to extend the learning:

- Research the use of robotics in surgery.
- Conduct **Building A Prosthetic Arm** (a WiSTEM²D Student Activity focused on Design and Manufacturing). See: https://www.STEM2D.org/prosthetic
- Implement **Create It, Try It, Manufacture It** (a WiSTEM²D Student Activity focused on Design and Manufacturing). See: https://www.STEM2D.org/activities/#makeit
- Try **Cotton Ball Catapult** (a WiSTEM²D Student Activity focused on Design and Engineering). See: https://www.STEM2D.org/activities/#catapult

Key Words

- **Atraumatic:** causing minimal tissue injury
- **Concept:** an idea or general plan
- **Engineering:** the branch of science and technology concerned with the design, building, and use of engines, machines, and structures
- **Laparoscopy:** a surgical procedure in which a fiber-optic instrument is inserted through the abdominal wall to view the organs in the abdomen or to permit a surgical procedure
- **Pilot:** activity or creation done as an experiment or test before introducing something more widely
- **Process:** a series of actions or steps taken in order to achieve a particular end
- **Profitable:** an activity yielding profit or financial gain
- **Prototype:** a simple model that lets you test your idea
- **Sterilization:** the process of making something free from bacteria or other living microorganisms
- **Sustained:** able to be prolonged for an extended period or without interruption
- **Trocar:** a pen-shaped surgical instrument with a sharp, three-sided (triangular) cutting point at one end

Resources and References

The following resources provide additional information or activities:

- Automation, Innovation, and Business—STEM for Kids: https://stemforkids.net/programs/advanced-manufacturing/
- Introducing the Design Process: https://pbskids.org/designsquad/pdf/parentseducators/DS_TG_DesignProcess.pdf
- Tackle the Engineering Design Process—with Kids: https://stemactivitiesforkids.com/2016/02/25/690/
- Video: The Engineering Design Process—A Taco Party: https://www.youtube.com/watch?v=MAhpfFt_mWM
- Video: Kid Engineer—The Design Process Design Squad: https://www.youtube.com/watch?v=FuzmxrqqBLc

PRE-ACTIVITY CHECKLIST:

BUILDING A MEDICAL DEVICE

*The following checklist helps activity leaders plan and prepare to conduct the **Building a Medical Device** activity with students.*

DID YOU...

- ☐ Read Spark WiSTEM²D? *This is essential reading for all volunteers interested in working with youth. It defines the STEM²D principles and philosophy and provides research-based strategies and tips for engaging and interacting with students. Download at www.STEM2D.org.*

- ☐ Visit the implementation site and observe the young people? *(optional)* If so, take note of the following:
  - ☐ How does the site encourage orderly participation? For example, do the young people raise their hands when responding to questions or during discussions? How are interruptions handled? Do you see any potential problems managing the class of young people?
  - ☐ What does the site do to make each student feel important and at ease?
  - ☐ How is the room arranged? Will you need to move desks or chairs for any part of your presentation?
  - ☐ How can you engage the site representative in your presentation?

- ☐ Meet with and finalize the logistics with the site representative?
  - ☐ Confirm the date, time, and location of the activity?
  - ☐ Confirm the technology needs? *Do you need to bring a computer and a projector to show the PowerPoint? Or, does the site have one that you can borrow? Does the site have Internet access? Can you use it during the activity to show the videos?*
  - ☐ Confirm the number of students attending? *Knowing this will help you decide how to separate the class into teams, as well as the appropriate materials to purchase.*

- ☐ Recruit two additional volunteers?
- ☐ Prepare for the activity? Did you:
  - ☐ Read the entire activity text prior to implementation?
  - ☐ Customize the activity and tailor the PowerPoint, if desired, to reflect your background and experiences, as well as the cultural norms and language of the students in your community?
  - ☐ Review the notes section of the slides in the PowerPoint for information to be shared?
  - ☐ Pre-view the video? *(optional)*

- ☐ Complete the Tell My Story Form, which will prepare you to talk about your educational and career path with the students? *If desired, include key points about your story on the PowerPoint (see **Tell My Story Slide**).*

☐ Practice your presentation, including the hands-on, minds-on activity? Be sure to:

- ☐ Do the activity; make sure you are able to explain the concepts to students, if needed, and that you know the correct answers.

☐ Obtain the required materials? (see the ***Materials*** and ***Estimated Materials Costs*** sections)

- ☐ Set up the site appropriately for the activity? Specifically:
- ☐ Make sure tables and chairs are arranged to accommodate teams of five students.
- ☐ Fill the balloons with water. Do not make the balloons available until final performance testing.
- ☐ Fill the 5-gallon container with water.
- ☐ Designate an area for the Materials Store (a table with all challenge supplies that teams can purchase for the challenge). The Supplier will oversee the store.
- ☐ Designate a performance testing area (place the container and trocar where students can access them to test their devices).
- ☐ Set up the computer and projector for the PowerPoint presentation. Be sure that speakers and an Internet connection are available to show the video.
- ☐ Assign two volunteers for the roles of Supplier and Judge.
- ☐ If additional volunteers are available, assign adults to specific teams.
- ☐ Bring a camera, if desired, to take photographs.

☐ Obtain and collect permission slips and photo release forms for conducting the activity if applicable?

☐ **Have fun!**

Tell My Story Form

This form will help volunteers prepare to talk about their STEM²D interests, education, and career path in a relevant and personal way.

ABOUT YOU

Name: _____

Job Title: _____

Company: _____

When/Why did you become interested in STEM²D? _____

_____

What do you hope young people will get out of this activity? _____

_____

_____

FUN FACT

Share a little about your background. Ideas:

- Share a memory from childhood when you first had your spark or interest in STEM²D.
- Detail your journey, highlighting what you have tried, what you learned, steps to success, etc.
- Failures or setbacks are also great to talk about—difficulties, and/or challenges and how you overcame them.

EDUCATION AND CAREER PATH

What classes/courses did you take in secondary school and in college that helped or interested you most?_____

_____

_____

How did you know you wanted to pursue a STEM²D career?_____

_____

_____

What was your postsecondary path, including the institution you attended and your degree? *If you switched disciplines, make sure you explain why.* _____

_____

_____

What your current position entails. *Be sure to include how you use STEM²D during a typical work day.* _____

_____

_____

CHALLENGE SCORING FORM

The Judge should use this form (one per team) to confirm each team's prototype meets the stated product requirements.

BUILDING A MEDICAL DEVICE

CUSTOMER NEEDS	MEETS REQUIREMENTS? CHECK (✓) IF YES
Is it easy to use?	
Can it be used by the left and right hand?	
Can it safely push the tissue?	
Can the tip be seen?	

SAFETY STANDARDS	
Is it safe to use on tissue?	
Does it fit through an 18 mm trocar?	
Is it long enough to fit through a 15 cm long port?	
Does it stay assembled when immersed?	

BUSINESS CONSTRAINTS/REQUIREMENTS	
Does it have a name?	
Are detailed designs provided?	
Does it meet 20% COGs?	
Is a tracking sticker attached?	

TOTAL YESES (✓)	

CHALLENGE

The Challenge:

Work as a team to design a medical device prototype that meets the specified requirements.

The Tasks:

1. Work as a team.
2. Assign each member a specific role.
3. Design a prototype that meets all product requirements.
4. Build the prototype using only the supplies available for purchase from the Materials Store.
5. Determine the device name and identify the product's key selling points.
6. Present the prototype (3-minute presentation, maximum)

Product Requirements:

The device must meet the following requirements:

- **Customer Needs:**
  - Can push the tissue out of sight
  - Is easy to use
  - Is a natural extension of the hand
  - Can be used in the right or left hand
  - Tip of the device can be seen
- **Safety Standards:**
  - Is atraumatic—does no damage to the tissue
  - Fits through an 18 mm trocar
  - Is long enough to extend through a 15 cm port
  - Stays assembled when immersed in water for one minute
- **Business Criteria:**
  - Has a name and detailed designs—for patent application
  - Is cost efficient—the sales price is $20.00, maximum
  - Is profitable—the Cost of Goods (COGs) is less than 20% of the sales price ($16.00 maximum)
  - Includes a Tracking Sticker

Team Roles & Responsibilities:

Before any designing and building takes places, determine each team member's role:

- **Design Engineer:** Develops a concept that meets the customer's needs
- **Procurement Manager:** Purchases and tracks all materials used and costs
- **Manufacturing Engineer:** Builds the initial prototype using the design concept and makes modifications (or rebuilds) the prototype to ensure the prototype is functional and meets safety standards
- **Quality / Testing Analyst:** Tests and evaluates each prototype to ensure functionality and product safety
- **Marketing and Sales Manager:** Develops requirements for the product and means to sell it to the customer

Instructions:

The team has 50 minutes to design, build, and test a medical device prototype that meets the specific needs of the customers. Use the guidelines below:

- **Design Engineer.** The main responsibilities of your job are:
  - Understand the customers' needs
  - Propose an initial product design
  - Sketch possible designs for the new product
  - Communicate material needs to the Procurement Manager
  - Communicate design specifications to the Manufacturing Engineer
  - Redesign the device based on feedback from the other team members
- **Procurement Manager.** The main responsibilities of your job are:
  - Purchase the materials needed from the materials store
  - Track the materials purchased and used in all prototypes on the Cost of Materials form
  - Compute the total Cost of Materials
  - Return unused materials to the materials store. Make sure unused materials are not included on your Cost of Materials form.
- **Manufacturing Engineer.** The main responsibilities of your job are:
  - Communicate with the Design Engineer regarding design specifications
  - Verify the materials to be used to build the product
  - Build the product based on the designs sketched by the Design Engineer
  - Attach tracking sticker to product
  - Communicate any desired changes to the Design Engineer
  - Rebuild or make adjustments to the device based on design changes shared by the Design Engineer and the recommendations of the Quality / Testing Analyst

- **Quality / Testing Analyst.** The main responsibilities of your job are:
  - Test the product to ensure it fits through an 18 mm trocar
  - Test the product to ensure it can be used left and right handed
  - Test the product to ensure it is long enough to extend through a 15 cm long port
  - Test the product to ensure it can be used on tissue
  - Communicate any design changes to the Design Engineer and Manufacturing Engineer
  - Ensure tracking sticker is attached to product
  - Conduct Perform Testing in front of the judge at the end of the session
- **Marketing and Sales Manager.** The main responsibilities of your job are:
  - Communicate with all team members to learn about the materials, design process, manufacturing process, and quality testing process
  - Determine the device name
  - Identify the product's key selling points
  - Prepare the marketing presentation
  - Deliver the marketing presentation during the Performance Testing

COST OF GOODS FORM
Student Handout

Instructions:

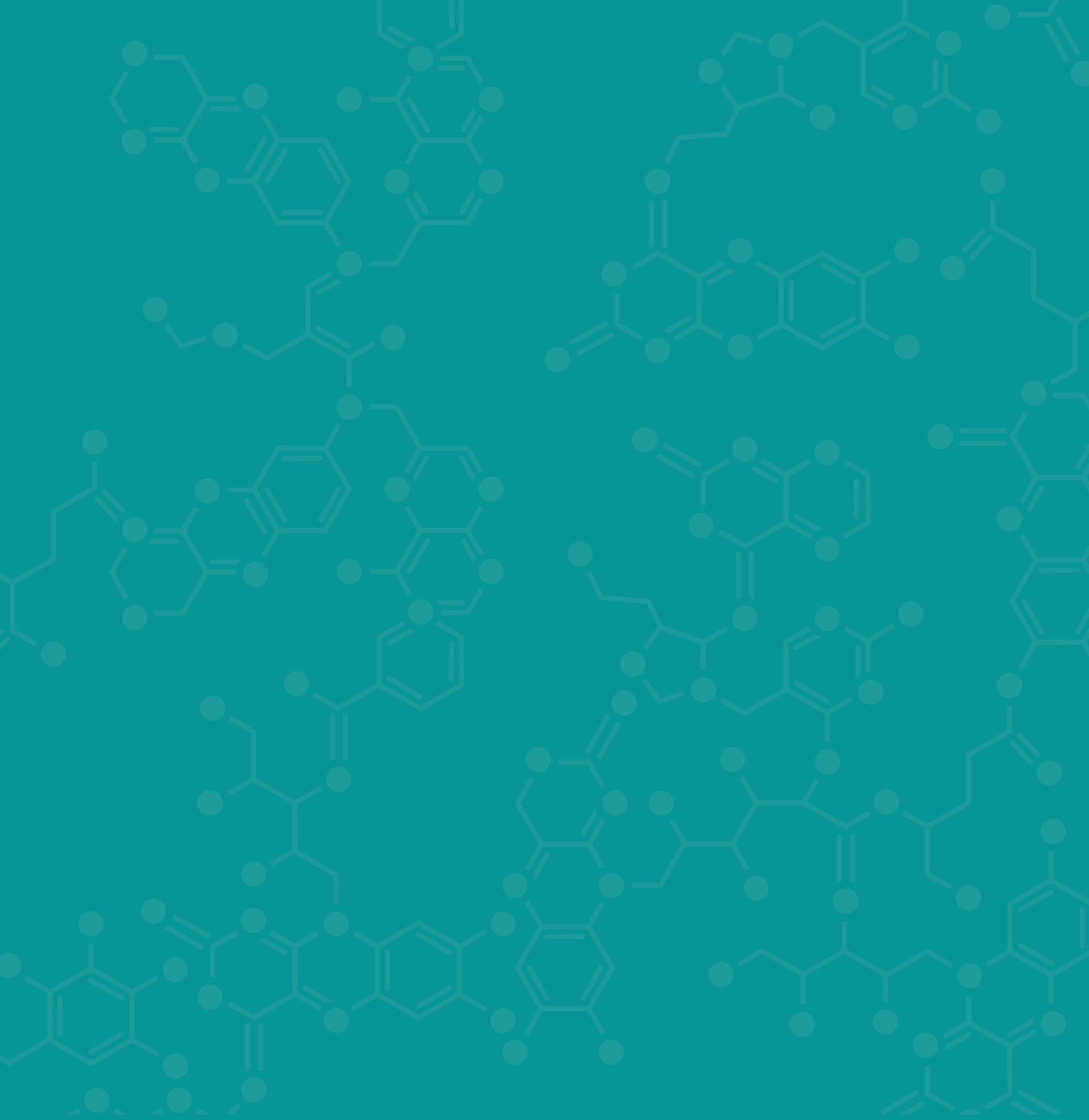
The Team Buyer should track the total items purchased and used for the prototype in the chart below. All supplies, including those used during testing and original prototypes, used must be recorded. Compute the total cost of each material used (Cost x No. Used = Total Cost per item), as well as the total cost (add the Total Cost column). Do not include unused (returned) materials on this form.

EXAMPLE:

ITEM	COST ($)	NO. USED	TOTAL COST ($)
Wood Skewer	$1.00	2	$2.00
Cotton Ball	$0.75	10	$7.50
Rubber Band	$0.50	5	$2.50
Electrical Tape	$0.25	10	$2.50
Circle Sticker	$0.05	3	$0.15
		TOTAL COST ($)	**$14.65**

ACTUAL:

ITEM	COST ($)	NO. USED	TOTAL COST ($)
Wood Skewer	$1.00		
Pipe Cleaner	$0.75		
Cotton Ball	$0.75		
Plastic Straw	$0.65		
Plastic Bead	$0.65		
Wood Bead	$0.50		
Rubber Bands	$0.50		
Paper Clip	$0.50		
Electrical Tape (6 inches in length)	$0.25		
Glue	$0.20		
Glue Stick	$0.20		
Color Label	$0.20		
White Label	$0.20		
Star Sticker	$0.10		
Circle Sticker	$0.05		
		TOTAL COST ($)	



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