Title:	Policy Number: 400.04.02
UNIVERSAL PROTOCOL: SITE MARKING & TIME OUT PROCESS	**Page:** 1 of 4
Sponsored By: BayCare Ambulatory Surgery Centers	**Issued for:** Bardmoor Surgery Center BayCare Surgery Center Trinity Carillon Surgery Center Tampa Minimally Invasive Spine Surgery Center
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Approved by: C. Todd Jones, VP, Ambulatory Experience and Operations **Signature:** _____	

This policy is developed as a guideline to address general circumstances. There may be certain instances in which the exercise of professional judgment and/or discretion by the health care provider warrants taking other actions. This Universal Protocol: Site Marking and Time Out Process applies to the facilities listed above, which are governed by BayCare Health System, Inc. (the facilities listed above and BayCare Health System, Inc., collectively, "**BayCare**").

PURPOSE:

To promote patient safety by engaging all members of the patient care team and providing guidelines for verification of the correct patient, site, side, procedure and implants for invasive and surgical procedures.

POLICY:

Accurate patient and site identification procedures will be implemented in the pre-procedure area and prior to the start of any invasive/surgical procedure, including anesthesia blocks. Confirmation of the correct patient, site, side, procedure, and implant will be completed and documented in a collaborative manner by the team. The patient will be actively involved in the identification process. This process is not confined to the procedure room but applies to any location where an invasive procedure is performed.

PROCEDURE:

PRE-PROCEDURE:

The RN conducting the pre-procedure assessment will:

1. Verify the accuracy of the pre-procedure checklist including relevant documentation (e.g. history and physical, procedural consents, physician procedural order, surgery schedule, nursing assessment, pre-anesthesia assessment), diagnostic studies if applicable, implants, devices, and any special equipment requested.
2. Verify that the surgical consent matches the proceduralist's order and plan of care
3. Verify the identification of the patient verbally and by visually inspecting the patient's ID band for name and date of birth (DOB). Any additional ID bands are validated at this time (e.g., allergy band).
4. Confirm the patient's knowledge of the proposed scheduled/ordered procedure.
5. Verify the patient's acknowledgment of the correct procedural site and side (left or right, when indicated).

The surgeon/procedural physician will:

1. Verify the identification of the patient verbally and by visually inspecting the patient's ID band for name and date of birth (DOB). Any additional ID bands are validated at this time (e.g., allergy band).
2. Verify the patient's knowledge of the proposed scheduled/ordered procedure.
   Confirm the patient's acknowledgment of the correct procedural site and side (left or right, when indicated).
3. Mark the procedure site, right or left side or digit, as appropriate.

An anesthesiologist, physician or pre-operative team member needing to perform or assist with treatment/procedures (e.g. anesthesia block, eye medications), prior to the site being marked must follow the verification process as outlined above. This does not preclude the procedural physician from again marking the site.

MARKING THE SITE:

1. Marking the site is required for all procedures/surgeries with laterality (e.g., left or right), multiple structures (e.g., fingers and toes) or multiple levels (e.g., pain management procedures, cervical, thoracic, and lumbar). The nurse and the surgeon will ask the patient to identify and to confirm the correct operative site(s). See exceptions from marking the site below.
2. The procedure site is marked before the patient is moved to the location where the procedure will be performed.
3. Marking the procedure site takes place with the patient involved, awake and aware. In cases of non-speaking, comatose, incompetent patients, or children, whoever has the authority to provide consent for the patient to undergo the procedure would, as appropriate, actively participate in the site marking process when possible. If a competent patient refuses to have the site marked, the patient's physician will review the rationale for site marking with the patient. If the patient still refuses site marking, an alternative method should be used before the procedure can proceed. Details of the refusal and any subsequent actions will be documented by both the proceduralist and the nurse and reported using the PRISM system.
4. The site will be marked with a "YES" or the physician's initials, preferably both, within 2 inches of the incision site with a permanent marker pen by the physician performing the procedure or his/her designee, who must be a licensed independent practitioner who is privileged and will be involved in the case. For specific guidance on anesthesia blocks, please see numbers 9-11 below.
5. The color marker pen will contrast to the patient's skin pigmentation. Do **NOT** mark the non-operative site.
6. For surgical procedures involving the ear, face or eye, a non-permanent marker should be used. Operative procedures that involve digits of the hands or feet will require that the specific digit be marked with a "**YES."** For children, digit marking will be adjusted based on patient age, size and cooperation.
7. When marking the site for correct side, multiple structures or multiple levels, the site marking must be visible after the patient is draped. The procedure will not commence until marking is visualized, unless technically or anatomically impossible or impractical to do so. In this situation, an alternative method must be used.
    a. Examples include but are not limited to:
        i. Re-marking by the physician
        ii. Utilization of a sterile, brightly colored "time out towel" to indicate laterality
        iii. Marking the correct side of the abdominal area for mid-line incisions or laparoscopic procedures with laterality
        iv. Marking of the thigh of the correct side for procedures with laterality through a single natural body orifice located below the waist and then drape with a clear legging.
        v. Utilization of a Velcro arm band containing the word "yes" placed by the proceduralist on the same side as the procedure site for infants less than 40 weeks of age who cannot have the site marked due to risk of permanent tattoo.
        vi. Utilization of a laminated "right" or "left" sign in the room which is visible to everyone.
8. Any discrepancy between the operative procedure and/or operative site, consent, order, plan of care or surgery schedule will necessitate immediate notification of the attending surgeon/physician. The patient cannot proceed to the procedural area until accurate verification is completed. After the discrepancy is resolved, a new consent form is re-affirmed with the patient.
9. Marking the regional block site takes place with the patient or patient's representative involved and is confirmed with the surgical consent.
10. Regional nerve blocks/procedures with laterality, require that the anesthesia provider that is performing the block mark the correct site as close in proximity as possible to block site with an "A" inside a circle during the Time-Out process.
11. If the regional block is to be performed after the patient is sedated, mark the block site before sedation.

Exceptions from site marking:

- Single Organ cases
- Single device removal (e.g., port removal on patient with 1 port).
- Teeth -BUT, indicate operative tooth name(s) on documentation, or mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Procedures performed through the mouth, anus or urinary or gynecologic orifices.
- Infants less than 40 weeks corrected age for whom the mark may cause a permanent tattoo
- The patient is emotionally or developmentally challenged; site may be marked after patient is sedated or under anesthesia.

“TIME OUT” FINAL VERIFICATION PROCESS:

In the procedure room, a robust “TIME OUT will include **participation from every member of the surgical team**. The surgical team includes: The Surgeon, Physician Assistant, Anesthesia Provider, Circulator, Surgical Technologist, Vendor, and any other person participating in the surgery. Once the patient is positioned/draped, prior to incision or invasive procedure, each member of the surgical/procedural team will **CEASE** all activity validate the following:

1. Correct patient identity (Patient name and DOB) verified from the patient’s armband (if not accessible, reverified from consent).
2. Correct side and site
3. Agreement on the procedure to be done. The procedure(s) written on the surgical consent will be read (and shown if needed) to the surgeon and the entire surgical/procedural team immediately prior to beginning the procedure.
4. Allergy status
5. Other elements to consider during time out are:
    - Correct patient position
    - Correct radiological exam results
    - Availability of correct implants, special equipment or instruments. Staff is validating the "availability" of implants only. **It is the physician's responsibility to validate correct implant(s) or review implant packing slip (i.e.; lens) to assure correct implants**.
    - Need to administer antibiotics IV or in irrigation fluids
    - Safety precautions based on patient’s history, allergies, or medication use.

The RN or designated health care professional assisting the proceduralist, reads the consent and remains in the surgical/procedure room until the incision is made or the procedure initiated.

At no time will the scalpel/sharps or pre-filled syringe be handed to the physician before the full verification process is complete and the entire surgical/procedural team are in agreement.

When performing multiple procedures or if a procedure(s) necessitates a change in surgeon / physician, this time-out process must be repeated. This confirmation will be documented on the appropriate form.

At the time any implant is opened the type, size and expiration date of implant will be verified by the operating room nurse, surgical technologist, and surgeon.

DISCREPANCIES:

Any discrepancy identified during the verification process necessitates immediate termination of the procedure until resolved. If there is disagreement among the team, the steps to resolve may include, but may not be limited to:

1. Re-verify against the patient’s medical record (documents to review include: booking sheet, consent, physician orders, and history and physical)
2. Patient’s verbal confirmation prior to case
3. Verify against physician office chart – on site or through phone call
4. Ask family member present or by phone
5. Escalate any discrepancies that cannot be resolved to site leadership

Any member of the team is empowered to say “STOP” and halt the process from moving forward because they know an error has been made or feel something is not right, without fear of retribution. If at any time a member of the team feels intimidated or threatened for speaking up, they are to contact their supervisor or any member of the leadership team immediately.

POST-PROCEDURE:

Post-Procedure confirm the following verbally prior to closure (if applicable) with licensed independent practitioner who performed the procedure:

1. Procedure performed verified and reconciled with consent (if applicable)
2. Instrument, sponge, and sharp count final result. See “Surgical Counts: Instruments, Sharps and Sponges Policy 400.09.03
3. Correct patient and specimen labeling validated by another member of the team and physician.
4. Wound classification confirmed verbally with physician.

"Universal Protocol" Declaration and Attestation

1. I hereby read and understand the Universal Protocol Policy. Once the patient is prepped and draped, but before incision, I will ensure that the "**Yes**" is visible unless technically or anatomically impossible to do so in which case I will use an alternative method listed above.

2. I will adhere to the Universal Protocol Policy for all procedures, without exception.

3. I understand that **AFTER** the patient is draped, I will require all room activities to cease while the **"TIME OUT"** is occurring and verbally/visually confirm each site along with the surgeon while the patient consent is read aloud.

4. I will ensure full attention of the room by calling a time out, safe identification of the patient, site, and side. I will get acknowledgment from all team members.

5. At no time will the scalpel/sharps or pre-filled syringe be handed to the surgeon before the consent is read aloud, and above procedures followed.

6. At the time any implant is opened the type, size and expiration date of implant will be verified by the operating room nurse, surgical technologist and surgeon.

_____	_____	_____
Print Name	Signature	Date / Time

This attestation may be used during orientation of new team members and physicians.