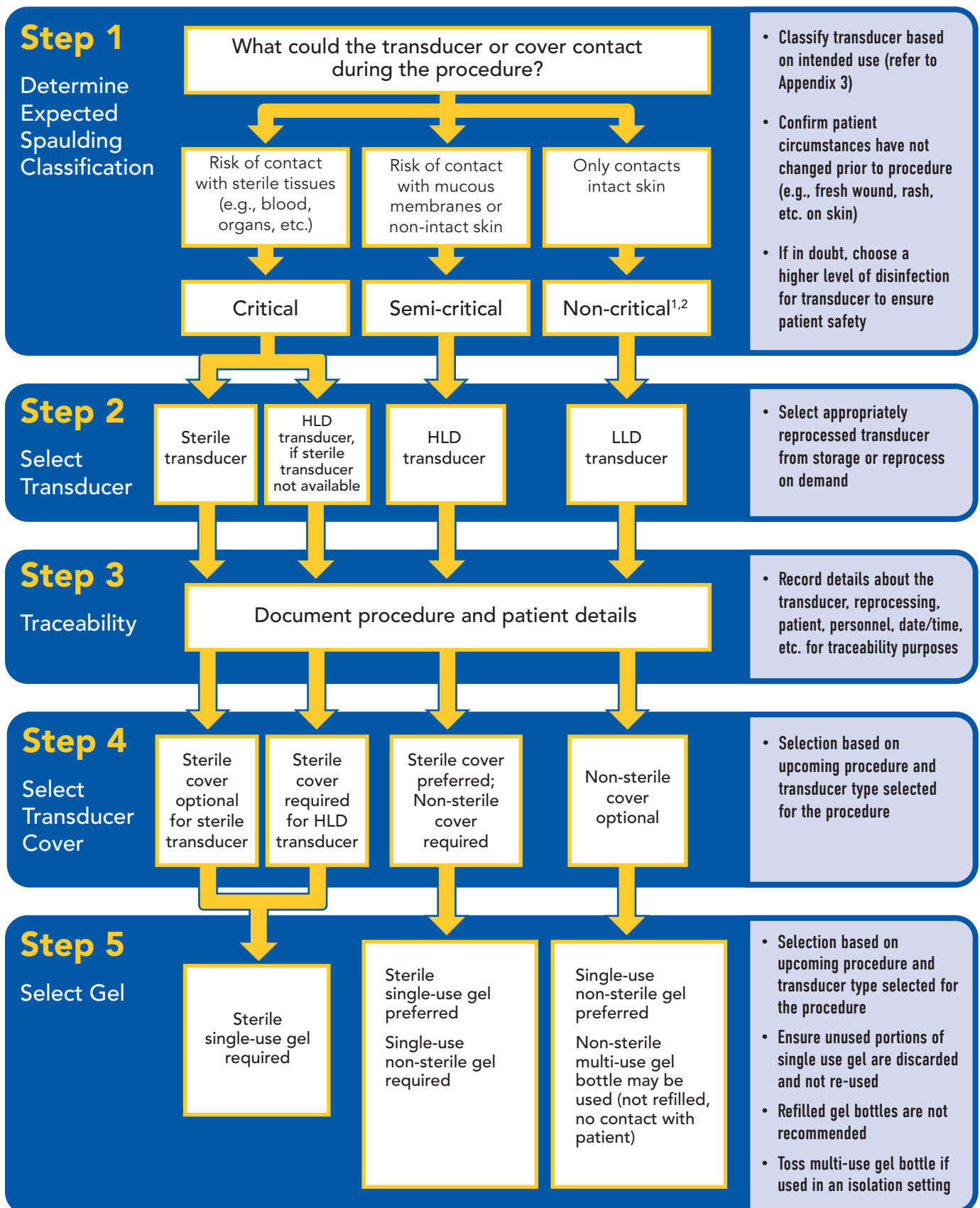


Appendix 1: Preparing for a Sonography Procedure

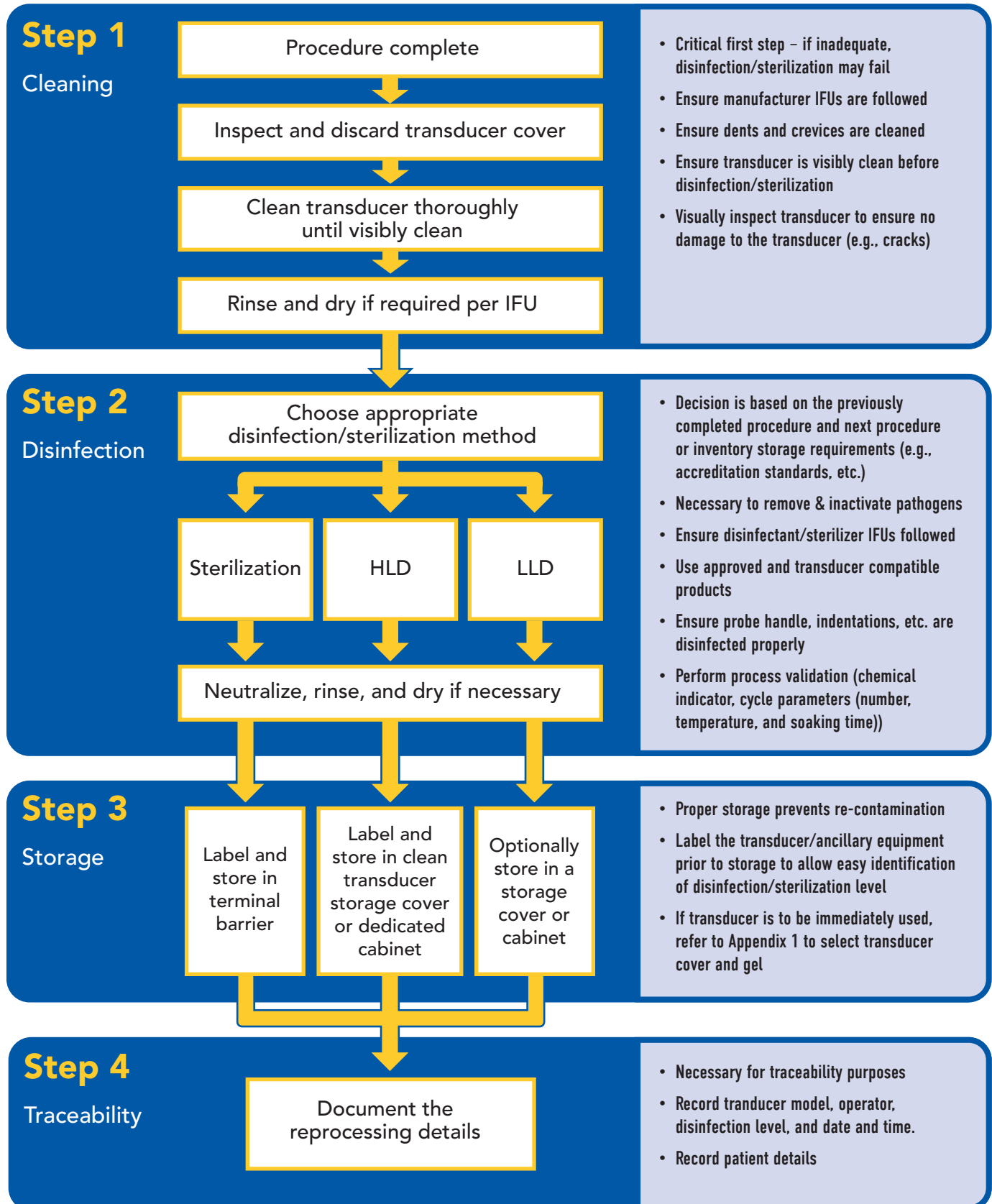


HLD = High Level Disinfection; LLD = Low Level Disinfection; Cover = Transducer Cover

¹ Non-Critical (Guidance¹) procedures require a transducer cover (type of procedure determines sterility) and sterile gel. The transducer may be LLD unless it comes in contact with mucous membranes, non-intact skin, sterile tissue or blood, which requires HLD. See Appendix 3.

² Non-Critical (Guidance²) procedures require a sterile transducer cover and sterile gel. The transducer may be LLD unless it comes in contact with mucous membranes, non-intact skin, sterile tissue or blood, which requires HLD. See Appendix 3.

Appendix 2: Reprocessing the Ultrasound Transducer and Ancillary Equipment



HLD = High Level Disinfection; LLD = Low Level Disinfection; Cover = Transducer Cover; IFU = Instructions for use

Appendix 3:

Sonography Procedures: Transducer Disinfection and Infection Control

The list of sonography procedures below describes the Spaulding Classification and best practices. Note that the expected Spaulding Classification for a sonography procedure could change upon patient condition (e.g., has open wound or infection in the scan area) or during the procedure (e.g., blood is present). Follow the same assessment of risk and Spaulding Classification for sonography procedures not listed.

| SONOGRAPHY PROCEDURES | EXPECTED: BEFORE PROCEDURE | | | KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed | | | | | | | | |
|--|---|------------------------------------|-------------------------|--|-------------------------|---------------------|---------------------|------------------|-------------|--------------------|-------------|--|
| PROCEDURE DESCRIPTION | ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH: | | | SPAULDING CLASSIFICATION | BEST PRACTICE | | | | | | | |
| | Intact Skin | Mucous Membrane or Non-Intact Skin | Sterile Tissue or Blood | | TRANSDUCER REPROCESSING | | | TRANSDUCER COVER | | COUPLING AGENT/GEL | | |
| | | | | | Clean & Sterile Process | Clean & HLD Process | Clean & LLD Process | Sterile | Non-Sterile | Sterile | Non-Sterile | |
| HEAD/NECK | | | | | | | | | | | | |
| Neck, Thyroid/Parathyroid | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Neonatal Brain (Echoencephalography) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Ophthalmic | | X | | Semi-Critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ | |
| Spinal Canal & Contents | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| CHEST/BREAST | | | | | | | | | | | | |
| Breast w/ axilla | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Chest (includes mediastinum, chest wall, and upper back) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| EXTREMITIES | | | | | | | | | | | | |
| Infant Hips | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Non-Vascular Extremity | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| ABDOMEN | | | | | | | | | | | | |
| Abdomen | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Abdomen Elastography | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Aorta (AAA screening) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Renal Retroperitoneal | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Retroperitoneal - Transplanted Kidney w/ Duplex Doppler | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Scrotum & Testicles | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Transrectal | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ | |
| Transrectal, Prostate | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ | |
| NON-OBSTETRICAL PELVIC | | | | | | | | | | | | |
| Pelvic (non-OB, transvaginal) | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ | |
| Sonohysterography w/ Doppler (non-OB, transvaginal) | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ | |
| Pelvic (non-OB, transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| OBSTETRIC | | | | | | | | | | | | |
| Fetal Biophysical Profile | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |
| Fetal Middle Cerebral Artery (Doppler velocimetry) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* | |

| SONOGRAPHY PROCEDURES | EXPECTED: BEFORE PROCEDURE | | | KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed | | | | | | | | |
|-----------------------|---|------------------------------------|-------------------------|--|-------------------------|---------------------|---------------------|------------------|-------------|--------------------|-------------|--|
| PROCEDURE DESCRIPTION | ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH: | | | SPAULDING CLASSIFICATION | BEST PRACTICE | | | | | | | |
| | Intact Skin | Mucous Membrane or Non-Intact Skin | Sterile Tissue or Blood | | TRANSDUCER REPROCESSING | | | TRANSDUCER COVER | | COUPLING AGENT/GEL | | |
| | | | | | Clean & Sterile Process | Clean & HLD Process | Clean & LLD Process | Sterile | Non-Sterile | Sterile | Non-Sterile | |

| OBSTETRIC (continued) | | | | | | | | | | | |
|---|---|---|--|---------------|----------|----------|----|----------|----------|----------|----|
| Fetal Umbilical Artery (Doppler velocimetry) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant (transvaginal) | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Pregnant < 14 weeks (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant > 14 weeks (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant w/ Detailed Fetal Anatomic Exam (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant w/ First Trim Fetal Nuchal Translucency (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Pregnant w/ First Trim Fetal Nuchal Translucency (transvaginal) | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |

| ECHOCARDIOGRAPHY (FETAL) | | | | | | | | | | | |
|------------------------------------|---|---|--|---------------|----------|----------|----|----------|----------|----------|----|
| Fetal Doppler Echocardiography | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Fetal Echocardiography (2D) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| ECHOCARDIOGRAPHY (PEDIATRIC/ADULT) | | | | | | | | | | | |
| Doppler Echocardiography | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Echocardiography (transesophageal) | | X | | Semi-Critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Echocardiography (transthoracic) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Stress Echocardiography | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Stress Echocardiography w/ ECG | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |

| VASCULAR | | | | | | | | | | | |
|--|---|---|--|---------------|----------|----------|----|----------|----------|----------|----|
| Abdominal Duplex Arterial/Venous (transabdominal) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Abdominal Duplex Arterial/Venous (transvaginal) | | X | | Semi-critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Carotid Intima-Media Thickness | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Carotid Doppler | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Aorta, IVC, Iliac, or Bypass Grafts | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Arterial/Venous Penile | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Lower Extremity Veins | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Upper Extremity Veins | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Hemodialysis Access | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Lower Extremity Arterial | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Duplex Upper Extremity Arterial Extracranial Arteries (duplex/Doppler) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Transcranial Doppler Intracranial Artery | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |

| SONOGRAPHY PROCEDURES | EXPECTED: BEFORE PROCEDURE | | | KEY: ✓* = Allowed/Preferred; ✓ = Allowed; ⊘ = Not Allowed | | | | | | | | |
|-----------------------|---|------------------------------------|-------------------------|--|-------------------------|---------------------|---------------------|------------------|-------------|--------------------|-------------|--|
| PROCEDURE DESCRIPTION | ASSESS RISK THAT THE TRANSDUCER (with or without a transducer cover) WILL COME IN CONTACT WITH: | | | SPAULDING CLASSIFICATION | BEST PRACTICE | | | | | | | |
| | Intact Skin | Mucous Membrane or Non-Intact Skin | Sterile Tissue or Blood | | TRANSDUCER REPROCESSING | | | TRANSDUCER COVER | | COUPLING AGENT/GEL | | |
| | | | | | Clean & Sterile Process | Clean & HLD Process | Clean & LLD Process | Sterile | Non-Sterile | Sterile | Non-Sterile | |

GUIDANCE

| | | | | | | | | | | | |
|--|---|---|---|---------------------------------------|----------|----|---|----|---|----|---|
| Abdominal Paracentesis | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Amniocentesis | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Arterial Pseudoaneurysms or Arteriovenous Fistulae | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Breast Biopsy, Localization Device | X | | | Non-Critical (Guidance ²) | optional | ✓* | ✓ | ✓* | ⊘ | ✓* | ⊘ |
| Breast, Localization Device | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Chorionic Villus Sampling | | X | | Semi-Critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Endomyocardial Biopsy | X | | | Non-Critical (Guidance ²) | optional | ✓* | ✓ | ✓* | ⊘ | ✓* | ⊘ |
| Endovenous Ablation w/ Laser | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Endovenous Ablation w/ Radiofrequency | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Fine Needle Aspiration Biopsy | X | | | Non-Critical (Guidance ²) | optional | ✓* | ✓ | ✓* | ⊘ | ✓* | ⊘ |
| Intraoperative | | | X | Critical | ✓* | ✓ | ⊘ | ✓* | ⊘ | ✓* | ⊘ |
| Intrauterine Fetal Transfusion or Cordocentesis | | X | | Semi-Critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Ova Aspiration (transvaginal) | | X | | Semi-Critical | optional | ✓* | ⊘ | ✓* | ✓ | ✓* | ✓ |
| Penile Injection with Vasoactive Agent | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Pericardiocentesis | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Peritoneal Lavage | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Pleural Drainage | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Radiation Therapy Placement | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Thoracentesis | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Tissue Ablation | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |
| Vascular Access | X | | | Non-Critical (Guidance ¹) | optional | ✓* | ✓ | ✓* | ✓ | ✓* | ⊘ |

OTHER

| | | | | | | | | | | | |
|--|---|--|---|--------------|----------|----------|----|----------|----------|----------|----|
| Assessment of Subclinical Atherosclerosis | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Cervical or Thoracic Injection | | | X | Critical | ✓* | ✓ | ⊘ | ✓* | ⊘ | ✓* | ⊘ |
| Cervical or Thoracic Transforaminal Epidural Injection | | | X | Critical | ✓* | ✓ | ⊘ | ✓* | ⊘ | ✓* | ⊘ |
| Contrast (non-cardiac) | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Elastography | X | | | Non-Critical | optional | optional | ✓* | optional | optional | optional | ✓* |
| Lumbar or Sacral Transforaminal Epidural Injection | | | X | Critical | ✓* | ✓ | ⊘ | ✓* | ⊘ | ✓* | ⊘ |

¹ Non-Critical (Guidance¹) procedures require a transducer cover (type of procedure determines sterility) and sterile gel. The transducer may be LLD unless it comes in contact with mucous membranes, non-intact skin, sterile tissue or blood, which requires HLD.

² Non-Critical (Guidance²) procedures require a sterile transducer cover and sterile gel. The transducer may be LLD unless it comes in contact with mucous membranes, non-intact skin, sterile tissue or blood, which requires HLD.