

Ultrasound Infection Prevention Toolkit

Infection Prevention Toolkit

Prevention of Infection during
Ultrasound Probe Use and Reprocessing

<http://www.ultrasoundinfectionprevention.org/>

Foreword

This toolkit has been assembled in consultation with clinical experts with backgrounds in infection prevention and instrument reprocessing. The objective in developing this toolkit has been to provide a resource regarding infection prevention during the use and reprocessing of ultrasound probes.

The following individuals have contributed to the development of this toolkit:

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Approach and Principles

These tools have been assembled based on best practice guidelines with the goal of reducing infection risks associated with ultrasound use in the interest of patient safety. Guidelines referenced in this toolkit are evidence-based, have been developed with infection prevention representation and have followed a formal guideline development process, including a public comment period. These tools are intended to guide the development of institutional policies and procedures, with an understanding that each institution can vary in the patient groups cared for, settings and the types of care provided.

Contents

Tool 1: Part A - Locate

This list of strategies can help locate ultrasound machines in your facility. Locating ultrasound machines can be a challenging task, as they may move around, be uncatalogued, or may be unknown to personnel with responsibility for probe use and reprocessing.

Tool 1: Part B - Profile

After locating ultrasound machines with the Locate tool, this audit tool can be used to observe and assess procedure-specific ultrasound policy and practice. First record the procedure and department, then work through the profile form. The questions guide the user through their policy and an observation checklist is provided to record actual practice. The tool leads the user to an action plan if there is no policy, or if there are discrepancies among policy, practice and guidelines.

Tool 2: Algorithm

This tool is organized by department and provides a range of typical procedures that may be encountered in that department. Probe use and reprocessing requirements based on federal guidelines (CDC and FDA) and national standards (AAMI) are presented as a decision-making algorithm. The flow chart can be printed out and displayed throughout office and procedure rooms and used as a quick reference chart for healthcare workers to determine whether practice is compliant with available guidelines.

Tool 3: Example Risk Assessment

This tool contains four editable templates designed to guide the assessment of potential hazards that may be encountered during the use and reprocessing (cleaning, disinfection, storage) of ultrasound probes. A sample risk matrix is provided with further instructions for completion. A facility should aim to mitigate all significant harm to the lowest risk rating. If that is not possible, the existing workflow and/or products should be reconsidered.

Tool 4: Policy Development Framework

This tool is a policy development framework designed to help develop infection prevention policies for all settings where ultrasound technology is used and probes are reprocessed. It can be used to develop a universal hospital policy or a department-specific policy and has been developed based on major guidelines, standards and evidence-based scientific literature.

Funding

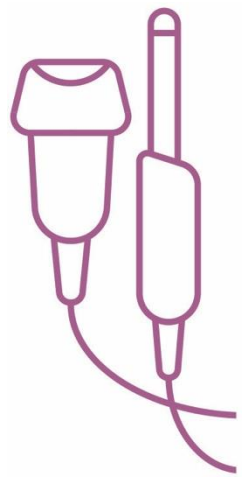
The development of this toolkit has been supported by Nanosonics Ltd. Nanosonics Ltd strives to improve the safety of patients, clinics, their staff and the environment by transforming the way infection prevention practices are understood and conducted and introducing innovative technologies that deliver improved standards of care.

Important Note

This toolkit contains general guidance. Consider this guidance in light of the user's own professional advice and specific regulations, guidelines, policies and procedures of each region, institution and department. This tool does not replace manufacturer instructions for use (IFUs), nor does it replace institutional policy/workflows, but it is intended to be used in conjunction with them. This Important Note applies to all parts of this toolkit.

Disclaimer

Nanosonics will not accept responsibility of any kind for reliance on this tool or related materials and opinions, including any death or injury to persons. The information, materials and opinions contained here are for general information purposes only, are not intended to constitute legal or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. We make no warranties, representations or undertakings about the content (including, without limitation, the quality, accuracy, completeness or fitness for any particular purpose of such content). This Disclaimer applies to all parts of this tool and every department.



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Tool 2

Algorithm

This tool is organized by department and provides a range of typical procedures that may be encountered in that department. Probe use and reprocessing requirements based on federal guidelines (CDC and FDA) and national standards (AAMI) are presented as a decision-making algorithm. The printable flow chart can be displayed throughout office and procedure rooms as a quick reference chart for healthcare workers to determine whether practice is compliant with available guidelines.

This tool can also be used in conjunction with Tool 1: Part B – Profile to determine whether policy and practice comply with best practice recommendations.

Guidelines

The following tool is based on the Spaulding classification system which is referenced in the Centers for Disease Control and Prevention (CDC) guidelines and American National Standards Institute (ANSI)/Association for the Advancement of Medical Instrumentation (AAMI) standards.^{1,2} The Centers for Medicare & Medicaid Services (CMS) and The Joint Commission (TJC) refer to these documents for accreditation of health care facilities, and are consistent with the US Food and Drug Administration (FDA) guidance documents.³⁻⁷

The Spaulding classification system dictates the level of disinfection or sterilization a medical device should be subjected to based on the degree of infection risk involved with its use and contact sites in patients. The definitions below are drawn from CDC, FDA and AAMI:

Non-critical devices – only contact intact patient skin and do not penetrate skin or contact mucous membranes. They require **low-level disinfection** (LLD).

Semi-critical devices – contact mucous membranes or non-intact skin, but do not ordinarily enter the bloodstream or other normally sterile areas of the body. Examples of non-intact skin include skin with cuts, abrasions, dermatitis, chapped skin, rash, psoriasis, broken skin, burns, cellulitis. At a minimum, they require **high-level disinfection** (HLD).

Critical devices – enter or contact sterile tissue, the bloodstream or are introduced into sterile body cavities during use. They require **sterilization**.

The classification of an ultrasound probe as a non-critical device is limited to use in external scans across healthy skin (e.g., transabdominal scans). Semi-critical ultrasound probes are those used in endocavitary scans (e.g., transvaginal, transrectal) and external scans with non-intact skin in the scan region. The CDC and FDA guidelines require semi-critical ultrasound probes to undergo high level disinfection.^{1,3} Critical ultrasound probes include those used in interventional procedures, such as surgeries in the operating room, minor procedures in interventional radiology, as well as probes used to guide percutaneous procedures where contact with the puncture site is possible (e.g., ultrasound guided biopsies, injections, cannulations). Invasive procedures confer a high risk of infection transmission as they access sterile body sites, requiring a sterile field and sterile instrumentation. If critical ultrasound probes cannot undergo

sterilization, the CDC provides the concession to minimally high-level disinfect these probes with use of a sterile sheath.¹ See Box 1 and 2 for excerpts from the CDC and FDA guidelines.^{1,3}

Box 1 (CDC¹): *“Ultrasound probes used during surgical procedures can contact sterile body sites. These probes can be covered with a sterile sheath to reduce the level of contamination on the probe and reduce the risk for infection. However, because the sheath does not completely protect the probe, the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.”*

Box 2 (FDA³): *“For clinical applications of a semi-critical or critical nature (e.g., intraoperative, transrectal, transvaginal, transesophageal, or biopsy procedures), labeling should recommend, when appropriate, the use of sterile, legally-marketed probe sheaths. Note that the use of sheaths does not change the type of reprocessing that is recommended after each use.”³*

Furthermore, the CDC and FDA instruct that the use of probe covers does not negate the need for high-level disinfection or sterilization (Box 3 and 4):^{1,3}

Box 3 (CDC¹): *“Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail.”*

Box 4 (FDA³): *“The probe used in a semi-critical application should be cleaned and sterilized or at least receive high-level disinfection after use even if a sheath was used. Probes used for critical applications should be cleaned and sterilized after use even if a sterile sheath was used. Sheaths can fail during use and the level of resulting contamination may not be easily visible.”*

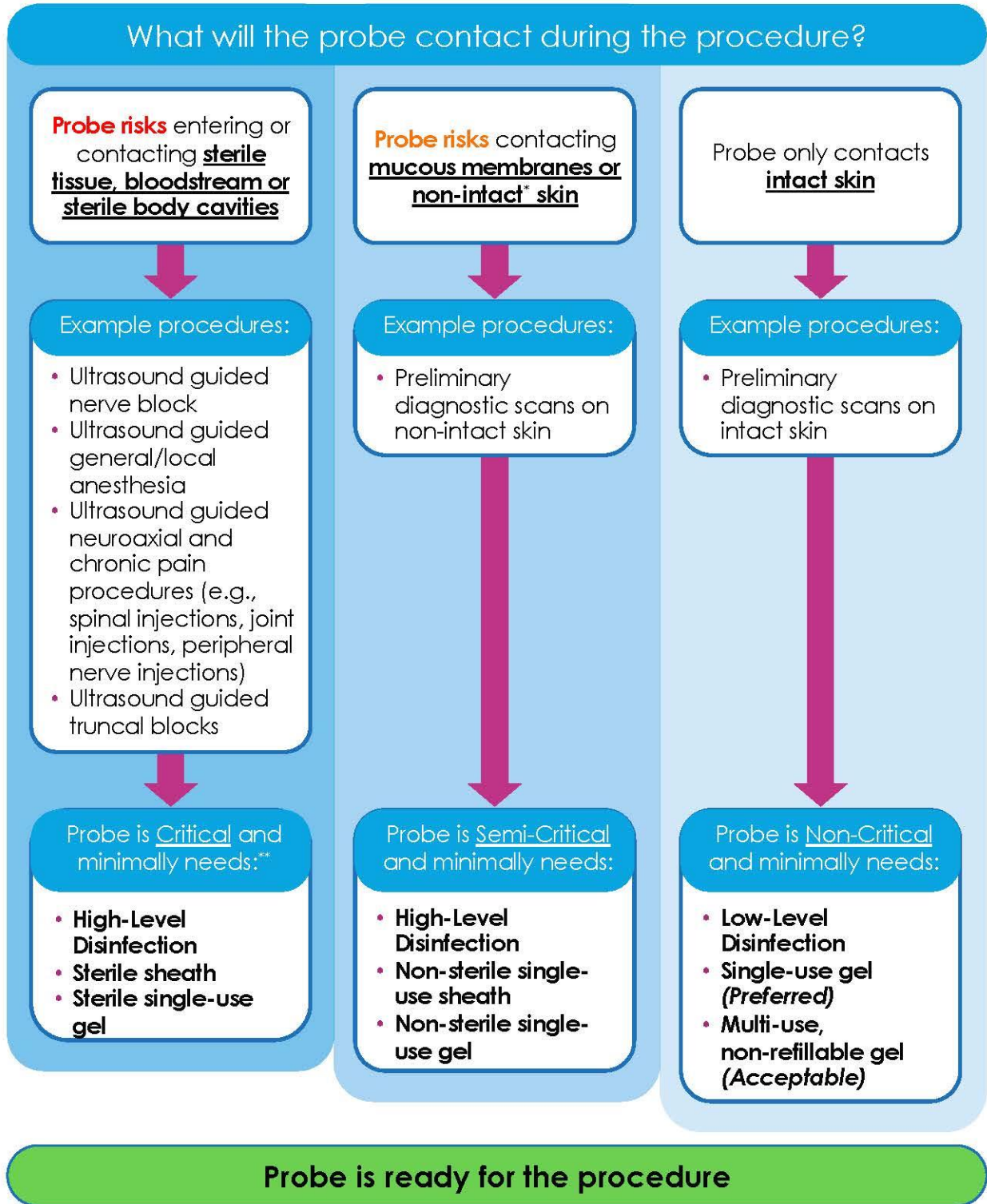
The following procedure charts are based on these recommendations and divided by department. Typical procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other Spaulding classification categories depending on the specific clinical situation and which tissues may be contacted. Print these charts and place them in treatment rooms to guide best practice ultrasound reprocessing and use for patient safety. Any deviation from best practice recommendations needs to be supported with clinical evidence and thorough risk profiling with a multidisciplinary assessment team and this process needs to be documented and reviewed according to hospital policy and procedure.

References

1. Rutala WA, Weber DJ, Healthcare Infection Control Practices Advisory Committee (HICPAC) & Centre for Disease Control and Prevention (CDC). Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008. Pages 19 and 89
2. American National Standards Institute (ANSI), Association for the Advancement of Medical Instrumentation (AAMI) ST58:2013 Chemical Sterilization And High-level Disinfection In Health Care Facilities. Page 109.
3. Food and Drug Administration (FDA). Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers. 2008. Pages 17 and 57. Available at: <https://www.fda.gov/downloads/UCM070911.pdf>
4. Centers for Medicare and Medicaid Services (CMS), 2015. Hospital Infection Control Worksheet Section 3.B., Page 23. Available at: <https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/downloads/survey-and-cert-letter-15-12-attachment-1.pdf>
5. Food and Drug Administration (FDA). Content and Format of Premarket Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants. 2000. Page 22. Available at: <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077575.pdf>
6. Food and Drug Administration (FDA). Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. 2015. Page 10. Available at: <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>
7. The Joint Commission (TJC), 2016. High-Level Disinfection (HLD) and Sterilization BoosterPak. Available at: https://www.jointcommission.org/assets/1/6/TJC_HLD_BoosterPak.pdf

Algorithm for Probe Use and Reprocessing in ANESTHESIOLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



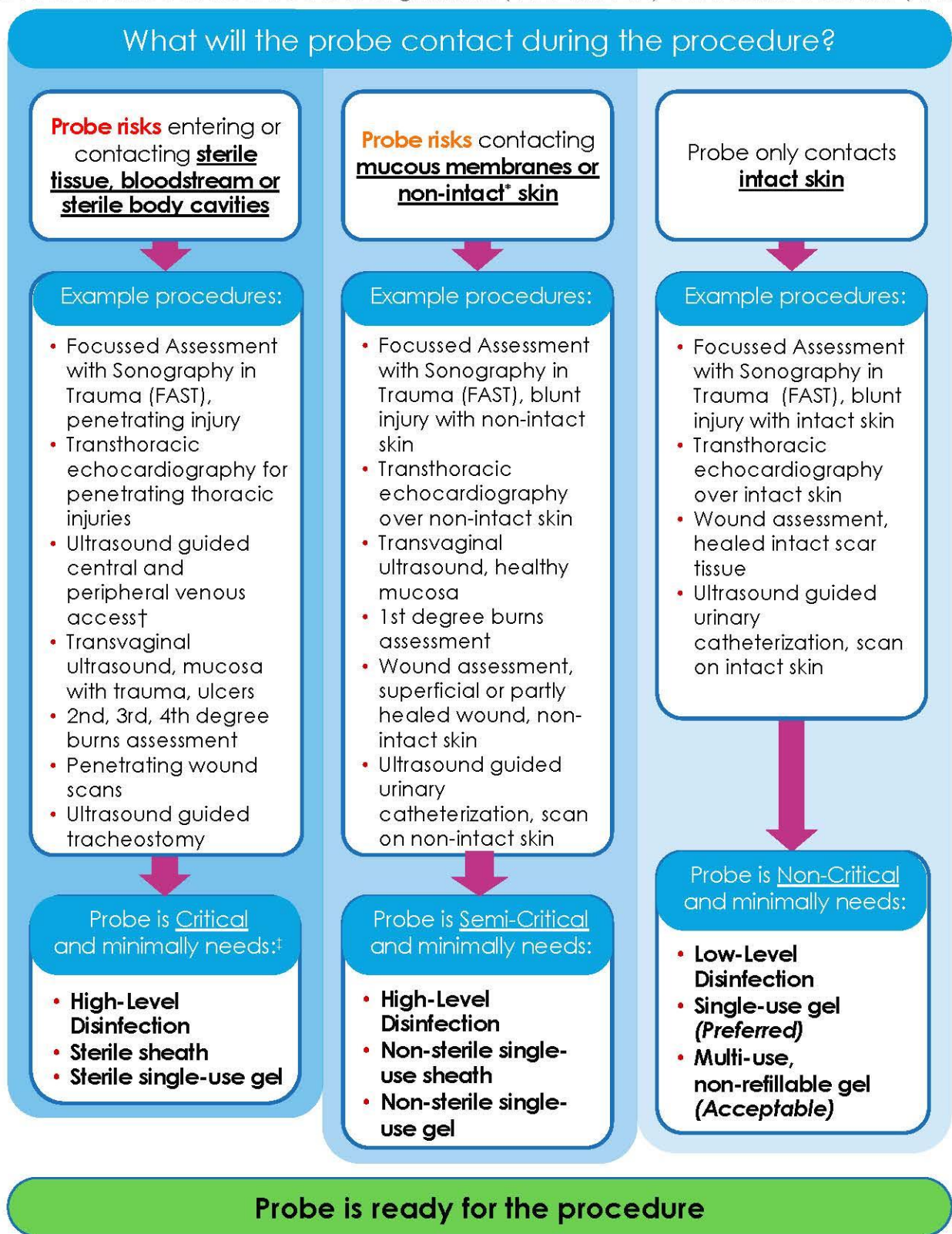
NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

*Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin or unhealthy skin etc.

**The CDC states that the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.

Algorithm for Probe Use and Reprocessing in EMERGENCY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

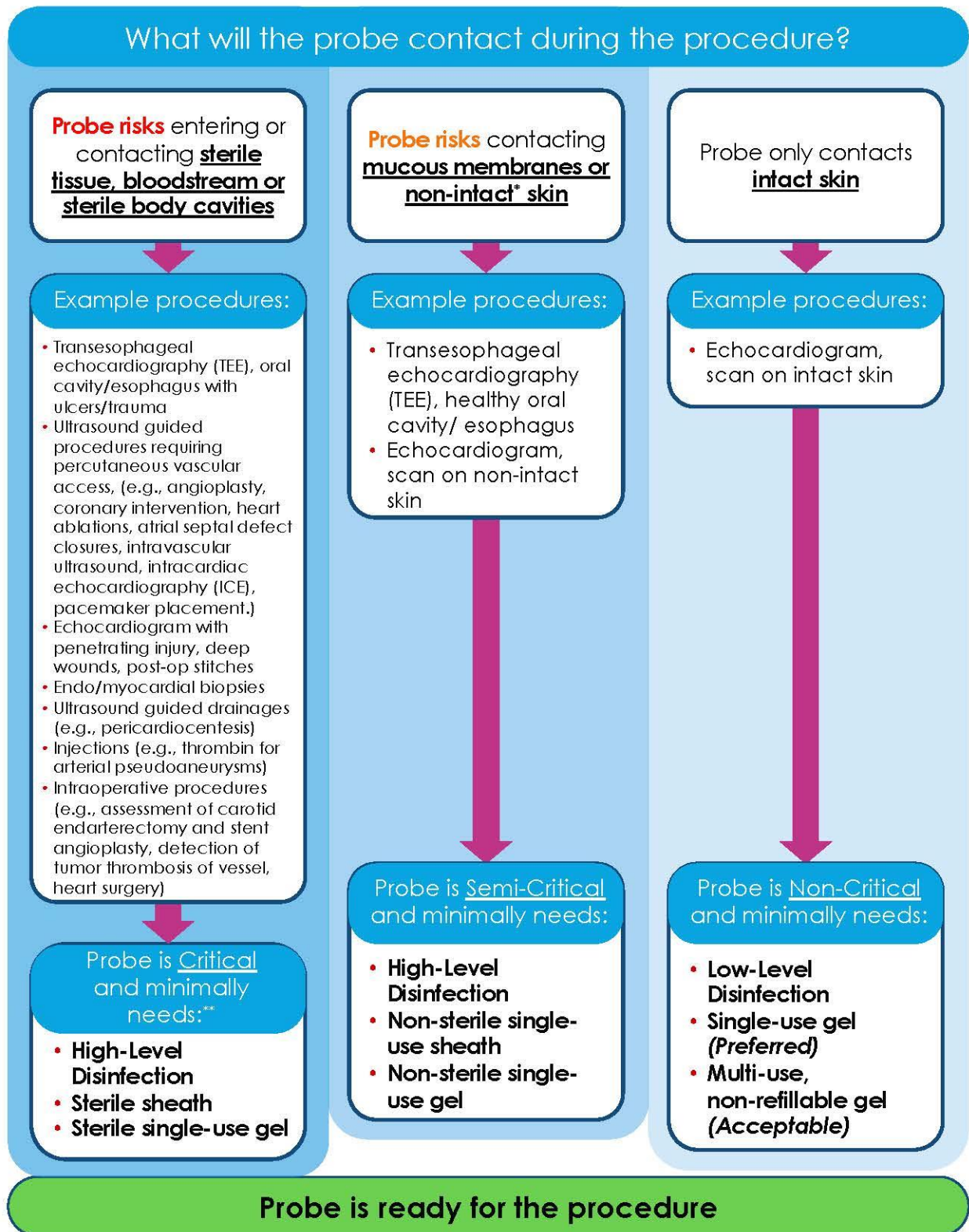
*Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin or unhealthy skin etc.

†It is important that patients continue to receive ultrasound guidance for peripheral IVs, midlines and PICCs as evidence shows increased risk of infection where ultrasound guidance is not performed. Where HLD would prevent the use of ultrasound for these procedures, the relative risks need to be considered. See Section 5.2.1 in Tool 4 – Policy Development Framework for more information.

‡The CDC states that the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.

Algorithm for Probe Use and Reprocessing in CARDIOLOGY

Based on recommendations from federal guidelines (CDC and FDA)
and national standards (AAMI).



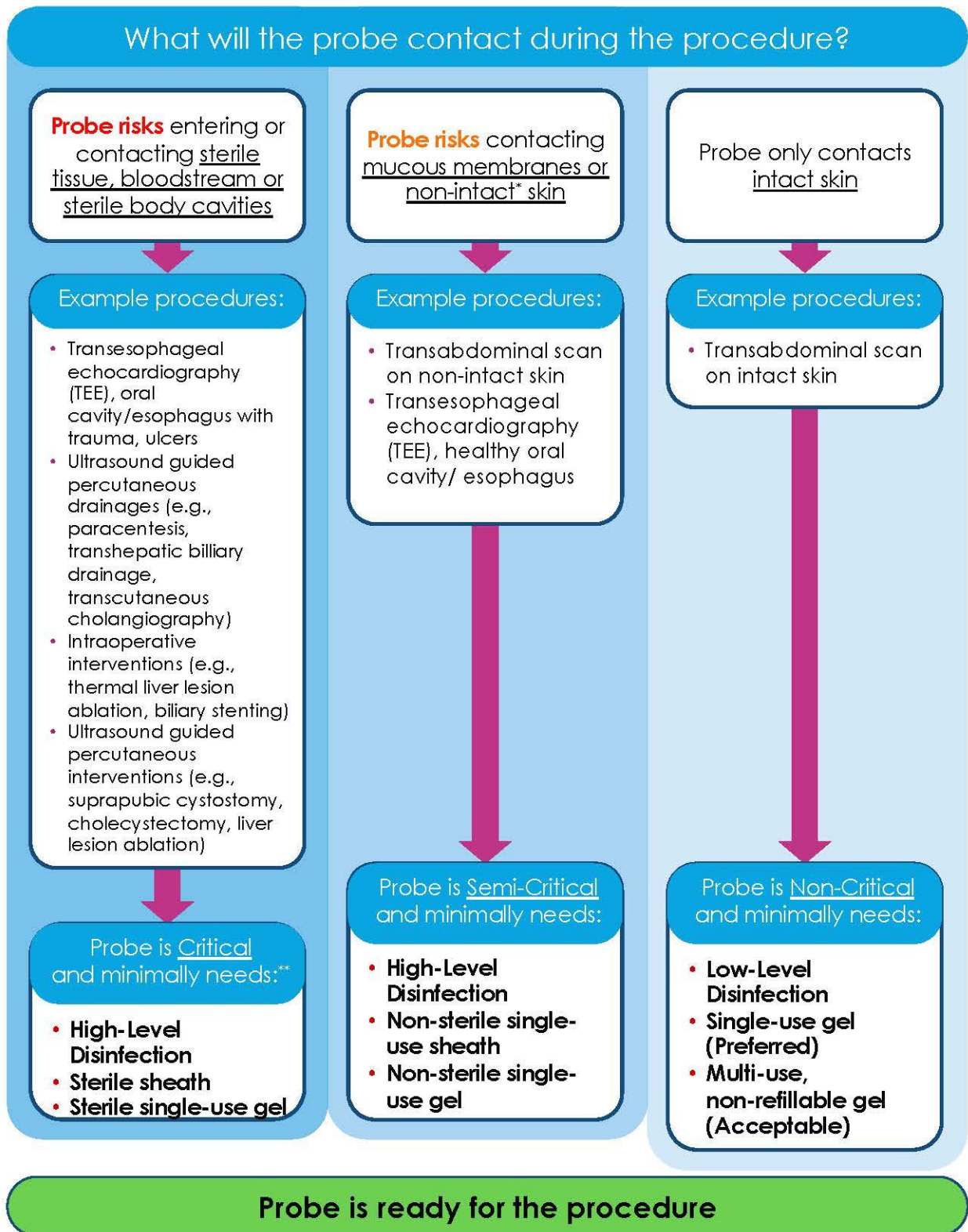
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*Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin or unhealthy skin etc.

**The CDC states that the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.

Algorithm for Probe Use and Reprocessing in GASTROENTEROLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



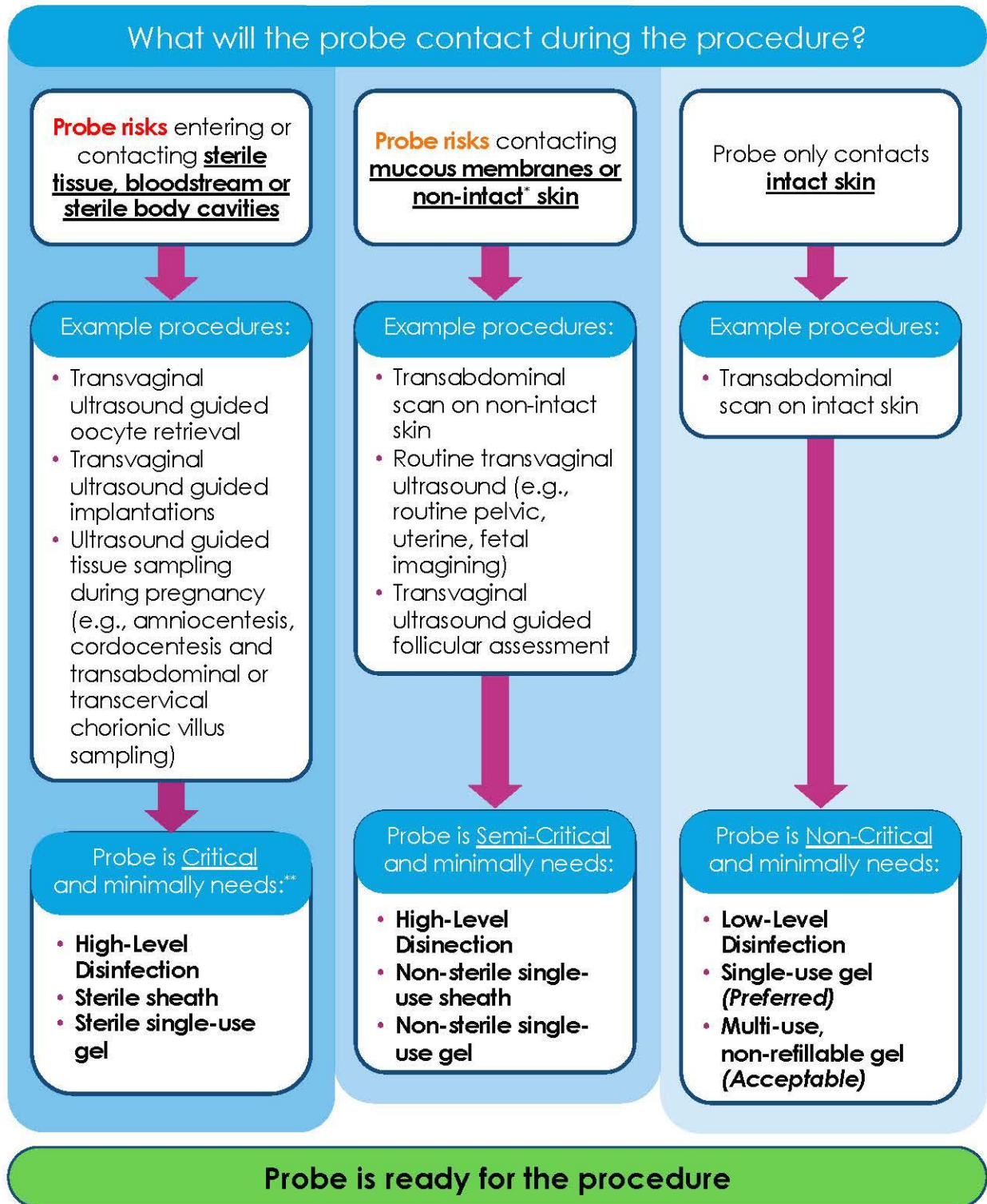
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Algorithm for Probe Use and Reprocessing in OBGYN/MFM

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



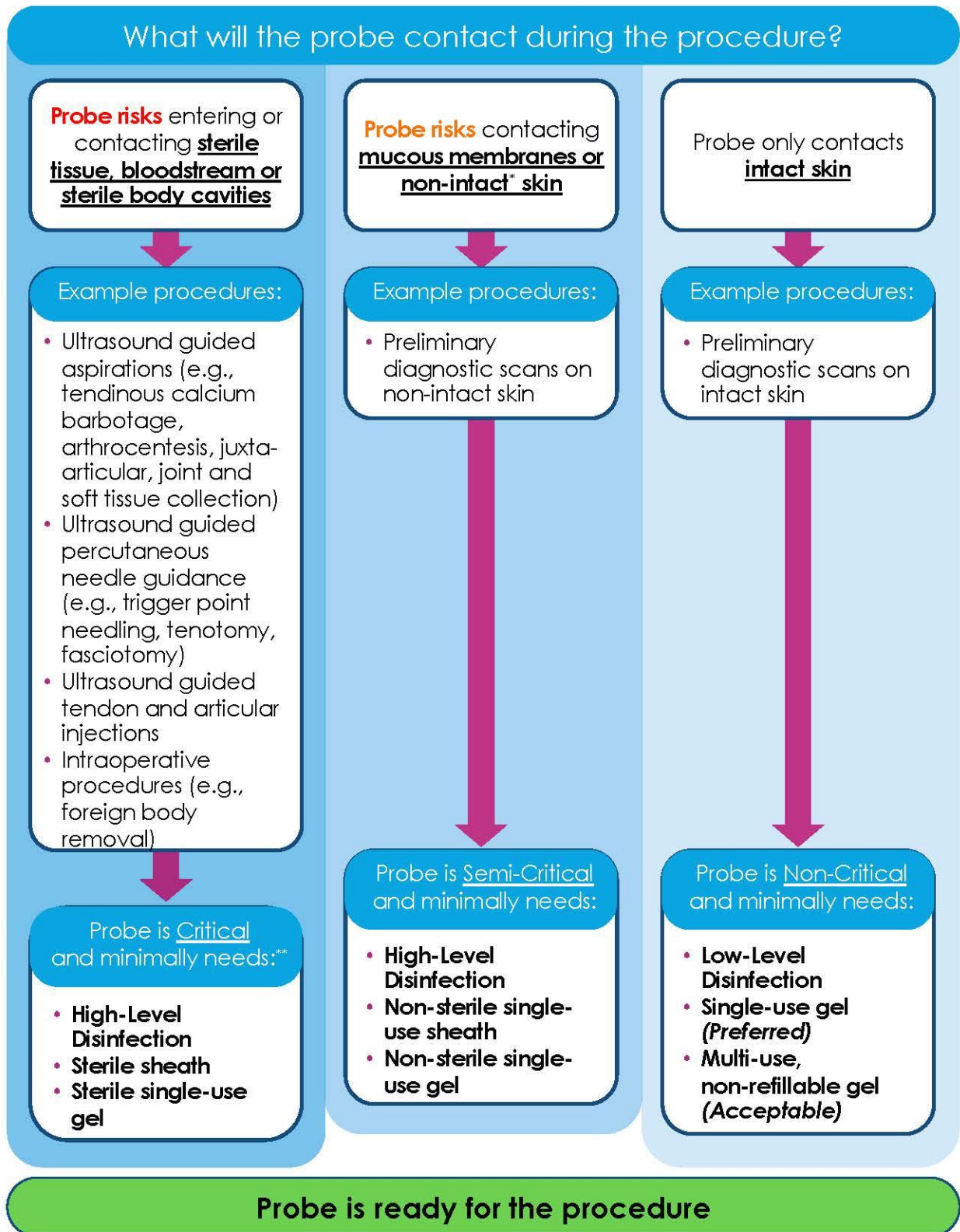
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Algorithm for Probe Use and Reprocessing in MUSCULOSKELETAL

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

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Algorithm for Probe Use and Reprocessing in NEPHROLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).

What will the probe contact during the procedure?

Probe risks entering or contacting sterile tissue, bloodstream or sterile body cavities

Example procedures:

- Diagnostic ultrasound (e.g., kidney stones, bladder health, prostatitis) in post-surgery patients with open wounds or fresh stitches near the scan region
- Ultrasound guided renal biopsy
- Ultrasound guided percutaneous nephrostomy

Probe is Critical and minimally needs:**

- **High-Level Disinfection**
- **Sterile sheath**
- **Sterile single-use gel**

Probe risks contacting mucous membranes or non-intact* skin

Example procedures:

- Diagnostic ultrasound (e.g., kidney stones, bladder health, prostatitis), scan on non-intact skin

Probe is Semi-Critical and minimally needs:

- **High-Level Disinfection**
- **Non-sterile single-use sheath**
- **Non-sterile single-use gel**

Probe only contacts intact skin

Example procedures:

- Diagnostic ultrasound (e.g., kidney stones, bladder health, prostatitis), scan on intact skin

Probe is Non-Critical and minimally needs:

- **Low-Level Disinfection**
- **Single-use gel (Preferred)**
- **Multi-use, non-refillable gel (Acceptable)**

Probe is ready for the procedure

NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

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Algorithm for Probe Use and Reprocessing in NEUROLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).

What will the probe contact during the procedure?

Probe risks entering or contacting **sterile tissue, bloodstream or sterile body cavities**

Example procedures:

- Ultrasound guided nerve blocks
- Ultrasound guided percutaneous needle guidance (e.g., peripheral nerve stimulation, spinal pain procedures)
- Ultrasound guided perineural catheter placement
- Intraoperative ultrasound in neurosurgery

Probe is **Critical** and minimally needs:**

- **High-Level Disinfection**
- **Sterile sheath**
- **Sterile single-use gel**

Probe risks contacting **mucous membranes or non-intact* skin**

Example procedures:

- Preliminary diagnostic scans on non-intact skin

Probe is **Semi-Critical** and minimally needs:

- **High-Level Disinfection**
- **Non-sterile single-use sheath**
- **Non-sterile single-use gel**

Probe only contacts **intact skin**

Example procedures:

- Preliminary diagnostic scans on intact skin

Probe is **Non-Critical** and minimally needs:

- **Low-Level Disinfection**
- **Single-use gel (Preferred)**
- **Multi-use, non-refillable gel (Acceptable)**

Probe is ready for the procedure

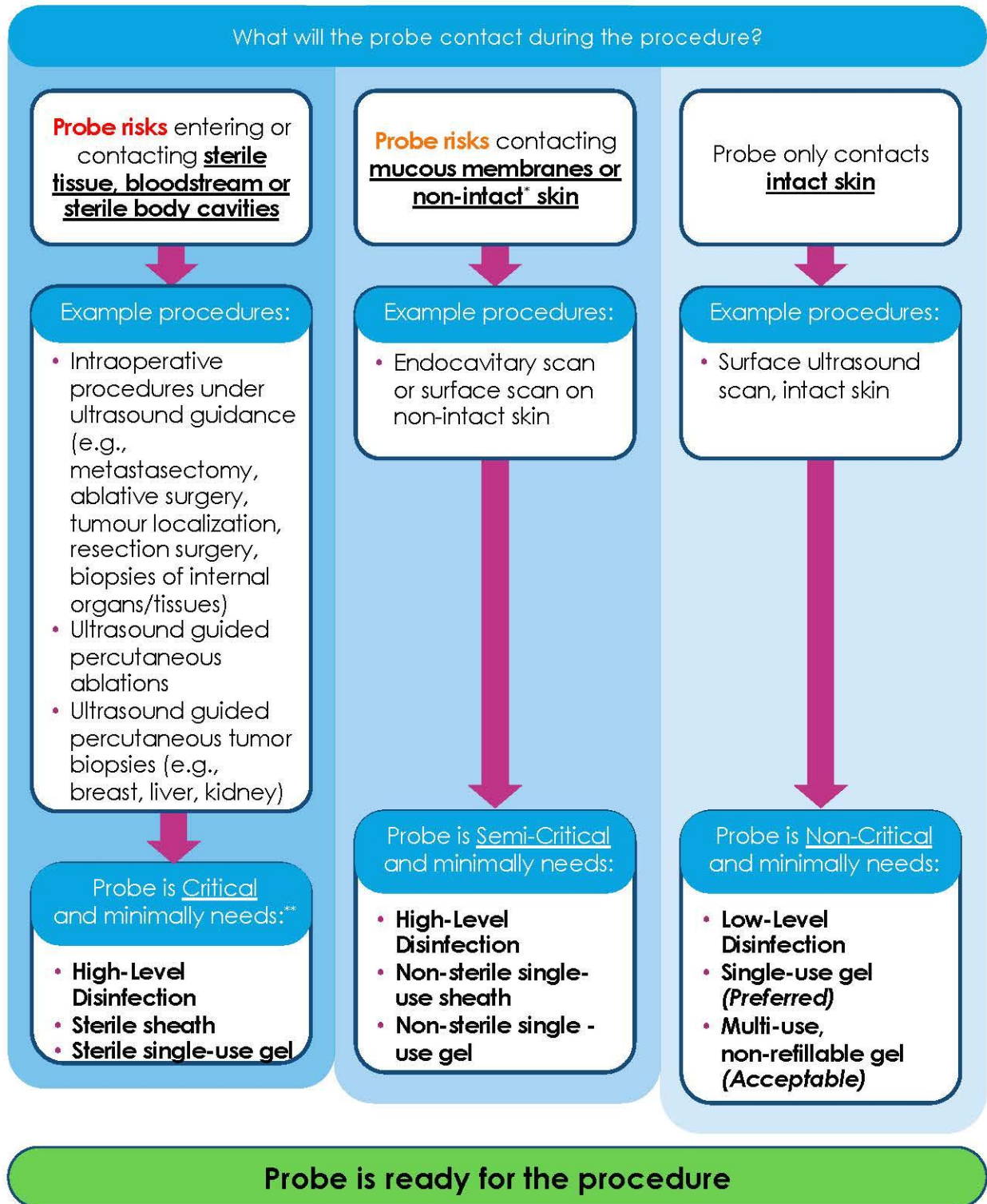
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Algorithm for Probe Use and Reprocessing in ONCOLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



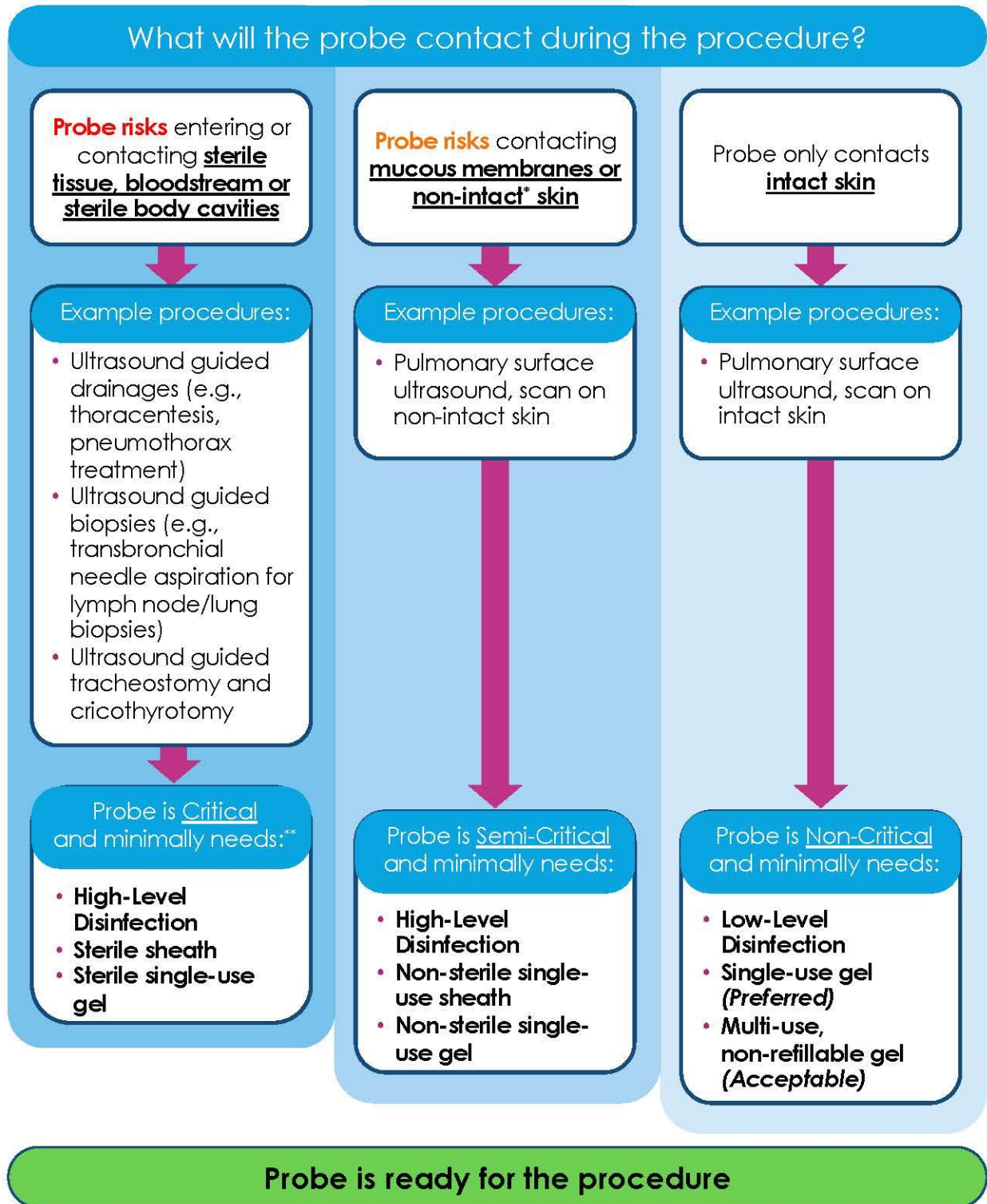
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Algorithm for Probe Use and Reprocessing in PULMONOLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).



NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

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Algorithm for Probe Use and Reprocessing in RADIOLOGY and INTERVENTIONAL RADIOLOGY

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).

What will the probe contact during the procedure?

Probe risks entering or contacting **sterile tissue, bloodstream or sterile body cavities**

Example procedures:

- Endocavitary ultrasound (e.g., transvaginal, transrectal), mucosa with trauma, ulcers
- Endocavitary ultrasound for interventional procedures (e.g., aspirations, biopsies)
- Ultrasound guided biopsies (e.g., liver, renal, breast, bone, lesion, lymph, prostate, chest/abdominal mass)
- Ultrasound guided aspirations and drainages (e.g., fluid, cyst and abscess aspirations, neck or thyroid mass aspirations)
- Ultrasound guided percutaneous ablations (e.g., liver lesions, vascular malformations)
- Intraoperative procedures (e.g., thrombectomy, breast surgery, hepatic tumor ablations, transplants, TIPSS)
- Foreign body localization/removal

Probe is **Critical** and minimally needs:**

- **High-Level Disinfection**
- **Sterile sheath**
- **Sterile single-use gel**

Probe risks contacting **mucous membranes or non-intact* skin**

Example procedures:

- Surface ultrasound (e.g., abdomen, breast, pelvis, neck, leg) on non-intact skin
- Endocavitary ultrasound (e.g., transvaginal, transrectal), healthy mucosa

Probe is **Semi-Critical** and minimally needs:

- **High-Level Disinfection**
- **Non-sterile single-use sheath**
- **Non-sterile single-use gel**

Probe only contacts **intact skin**

Example procedures:

- Surface ultrasound (e.g., abdomen, breast, pelvis, neck, leg) on intact skin

Probe is **Non-Critical** and minimally needs:

- **Low-Level Disinfection**
- **Single-use gel (Preferred)**
- **Multi-use, non-refillable gel (Acceptable)**

Probe is ready for the procedure

NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

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Algorithm for Probe Use and Reprocessing in UROLOGY

Based on recommendations from federal guidelines (CDC and FDA)
and national standards (AAMI).

What will the probe contact during the procedure?

Probe risks entering or contacting **sterile tissue, bloodstream or sterile body cavities**

Example procedures:

- Diagnostic surface ultrasound (e.g., kidney stones, bladder health, prostatitis, scrotum and testicular pathology) on post-op patients with open wounds or fresh stitches near the scan region
- Transrectal ultrasound, unhealthy mucosa (e.g., bleeding, ulcers)
- Transrectal ultrasound during interventional procedures (e.g., prostate biopsy, prostatitis treatment, catheterization)
- Ultrasound guided scrotal drainage; suprapubic bladder aspiration
- Ultrasound guided testicular biopsy

Probe is **Critical** and minimally needs:**

- **High-Level Disinfection**
- **Sterile sheath**
- **Sterile single-use gel**

Probe risks contacting **mucous membranes or non-intact* skin**

Example procedures:

- Diagnostic surface ultrasound (e.g., kidney stones, bladder health, prostatitis, scrotum and testicular pathology) on non-intact skin
- Transrectal ultrasound, healthy mucosa

Probe is **Semi-Critical** and minimally needs:

- **High-Level Disinfection**
- **Non-sterile single-use sheath**
- **Non-sterile single-use gel**

Probe only contacts **intact skin**

Example procedures:

- Diagnostic surface ultrasound (e.g., kidney stones, bladder health, prostatitis, scrotum and testicular pathology) on intact skin

Probe is **Non-Critical** and minimally needs:

- **Low-Level Disinfection**
- **Single-use gel (Preferred)**
- **Multi-use, non-refillable gel (Acceptable)**

Probe is ready for the procedure

NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

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Algorithm for Probe Use and Reprocessing in VASCULAR

Based on recommendations from federal guidelines (CDC and FDA) and national standards (AAMI).

What will the probe contact during the procedure?

Probe risks entering or contacting sterile tissue, bloodstream or sterile body cavities

Example procedures:

- Vascular access for angiogram, angioplasty, endovascular aneurysm repair
- Venous ablation
- Ultrasound guided central and peripheral venous access†

Probe is Critical and minimally needs:‡

- High-Level Disinfection
- Sterile sheath
- Sterile single-use gel

Probe risks contacting mucous membranes or non-intact* skin

Example procedures:

- Arterial/venous/carotid duplex or Doppler scan on non-intact skin

Probe is Semi-Critical and minimally needs:

- High-Level Disinfection
- Non-sterile single-use sheath
- Non-sterile single-use gel

Probe only contacts intact skin

Example procedures:

- Arterial/venous/carotid duplex or Doppler scan on intact skin

Probe is Non-Critical and minimally needs:

- Low-Level Disinfection
- Single-use gel (*Preferred*)
- Multi-use, non-refillable gel (*Acceptable*)

Probe is ready for the procedure

NOTE: Example procedures have been provided as examples based on interpretation of the Spaulding classification. Some procedures may fall into other categories depending on the specific clinical situation and on which tissues may be contacted. Additionally, the probe cable and ultrasound console are generally considered non-critical surfaces and should be cleaned and undergo LLD between patients as part of the room turnover process. Check with manufacturer to determine whether chosen disinfectant is compatible with the probe and cable.

*Non-intact skin: Areas of the skin that have been opened by cuts, abrasions, dermatitis, chapped skin or unhealthy skin etc.

†It is important that patients continue to receive ultrasound guidance for peripheral IVs, midlines and PICCs as evidence shows increased risk of infection where ultrasound guidance is not performed. Where HLD would prevent the use of ultrasound for these procedures, the relative risks need to be considered. See Section 5.2.1 in Tool 4 – Policy Development Framework for more information.

‡The CDC states that the probes should be sterilized between each patient use as with other critical items. If this is not possible, at a minimum the probe should be high-level disinfected and covered with a sterile probe cover.