

| Revision | Description of Change |
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| Item Number | Function | Risk Analysis | | | | | | Risk Control | | | | Risk/Benefit Analysis | Information/Comments | | |
|-------------|-----------------------------------|---|---|---|--|---------------------------------------|------------|--------------|--|----------|------------|-----------------------|----------------------|--------|---|
| | | HAZARD (Potential cause of Hazard) | Hazardous Situation | HARM (Potential adverse effect) | Cause | SEVERITY | OCCURRENCE | RPN | RISK MITIGATION | SEVERITY | OCCURRENCE | | | RPN | Risk reduced as far as possible? (afap) |
| Description | | Description of why the product will not perform conform specs | | Description of resulting injury, damage | | | | | The way by which the risk is reduced/ eliminated | | | | afap | Yes/No | e.g. IFU, labeling |
| Example | Debris or Fragment | Small fragment from device created during use | Fragment is swallowed and in GI tract | Fragment causes blockage requiring surgery | Material strength is too low and not designed for impact | | | | Material Specification of high impact polystyrene | | | | | | |
| 1 | Shape of finger flexor | Shape of finger flexor is not compatible with baby's arm | Size of finger loops is incorrect | Numbness/ nerve damage | Tight loops obstruct blood flow | 4 | 2 | 8 | Flexor has a strap to secure the grip | 2 | 2 | 4 | afap | Yes | |
| | | | Gripper/flexor slips off | Bruising | Material surface does not provide enough friction | 3 | 3 | 9 | | 2 | 2 | 4 | | Yes | |
| 2 | Attachment to finger flexor | Finger flexor is not securely attached to baby's arm | Baby yanks hand away from device, leading to high strain on arm | Skin soreness (abrasions) | Material surface too rough on baby skin (friction needed to prevent slipping) | 3 | 3 | 9 | | 2 | 2 | 4 | | Yes | |
| 3 | | | | | | | | | | | | | | | |
| 4 | Stiffness of finger flexor | Flexing puts too much pressure on patient arm | Need to grip for a long time | Tissue soreness | Patient has weak grip | 2 | 4 | 8 | Test for and specify the most effective range of compressive strength for material | 2 | 2 | 4 | afap | yes | |
| 5 | | | | Carpal tunnel injury | Material has (too) high compressive strength | 4 | 3 | 12 | | 2 | 1 | 2 | | yes | |
| 6 | | | | Flexor compresses easily | Veins do not appear | Material has low compressive strength | 4 | 4 | | 16 | 2 | 1 | | 2 | yes |
| 7 | Penetration depth of microneedles | Excessive pressure applied during blood draw | Microneedle breaks and enters baby's skin | Bruising causes discomfort, pain, and leads to more serious complications | Patch designed with too much pressure | 3 | 4 | 12 | Use stainless steel MNs | 2 | 1 | 2 | afap | yes | |
| 8 | Blood Sample | Needle prick or puncture | Baby experiences bleeding or infection at the puncture site | Pain, discomfort, infection, or bruising at the puncture site | Improper needle insertion, incorrect needle size, or insufficient sterilization of equipment or skin | 3 | 3 | 9 | | | | 0 | | | |
| 9 | Blood Sample | Transmission of Infectious disease | Contamination of the needle with bloodborne pathogens | Infection with hepatitis B, hepatitis C, HIV, or other bloodborne pathogens | Use of a contaminated needle or inadequate sterilization of the needle and surrounding skin | 4 | 2 | 8 | | | | 0 | | | |
| 10 | Blood Sample | Blood loss or anemia | Excessive or repeated blood drawing | Hemorrhage, anemia, or iron deficiency | Drawing too much blood, too often, or from a vein that is not suitable for blood collection. | 4 | 2 | 8 | | | | 0 | | | |

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| FINAL | Overall Residual Risk is Acceptable (Yes/No): | Yes |
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