

Rice 360 - Neonatal Mortality Research & Competitor Analysis

Focus: Low cost, locally manufacturable (3D printed) umbilical cord clamp

Executive Summary

- Neonatal deaths remain stubbornly high: ~2.3 million newborns died in 2023 globally; sub Saharan Africa has the highest burden. Nigeria's neonatal mortality rate is ~34 per 1,000 live births.
- Rice 360's NEST360 alliance focuses on systems strengthening, locally owned data, and appropriate technology to reduce preventable newborn deaths—an enabling ecosystem for essential low risk devices such as cord clamps.
- Conventional cord clamps are commodity devices with bulk prices typically \$0.50–\$1.60 per unit depending on brand, sterility, and order size. Local availability and stock outs remain issues in some facilities.
- A 3D printed clamp can improve supply resilience and reduce total delivered cost if design, materials, sterilization, QA, and clinical workflow alignment are addressed.
- Regulatory: Umbilical occlusion devices are generally Class I (e.g., FDA) with 510(k) exemptions, but ISO13485 QMS, ISO 10993 biocompatibility, and ISO 11607 packaging are still critical.

Neonatal Mortality Landscape

- Global: In 2023, ~2.3 million neonatal deaths occurred worldwide. Sub Saharan Africa has the highest neonatal mortality rate (~27 per 1,000).
- Nigeria: Neonatal mortality is ~34 per 1,000 live births, higher in rural and low income households. Main causes include prematurity, intrapartum complications, and infections.
- Cord care practice: WHO and ACOG recommend delayed cord clamping (typically 1–3 minutes). Clamps must maintain secure occlusion post delay as cords shrink.

Rice 360/NEST360 Contributions

NEST360 delivers newborn care ecosystems across African countries including equipment, training, maintenance, and data tools (e.g., the Neonatal Inpatient Dataset). These platforms can accelerate adoption and monitoring of essential disposables like cord clamps.

Design Goals for a 3D Printed Clamp

- Secure occlusion with constant pressure; no sharp edges; double lock; non reopen as cord

shrinks. Usable one handed with gloves; tactile/audible latch; hinge guard to confine cord.

- Material: biocompatible and sterilizable (EtO/steam compatible where possible); traceable lots. Manufacturability on FDM/resin printers; minimal post processing; simple test jigs.
- Quality & safety verification: occlusion/leak tests, tensile & latch strength, post sterilization verification, usability studies.

Competitor Landscape

Product / Brand	Features	Price	Market / Notes
Lister Double-Grip Clamp & Clipper	Grooved jaws, T-bar latch, hinge guard; dedicated clipper	Clipper ~\$30; clamp varies	Hospital standard in many Medline kits
Umbilical Cord Clamp (Generic)	Single-use plastic; sterile/non-sterile; sold in cases of 100	\$0.58–\$1.60 per clamp	Commodity device; widely available regionally
Royal/Kendall Cord Clamp / Clipper	Serrated jaws; sterile options	\$1.40+ per clamp	Established US brands
Giplast (India) Umbilical Cord Clamp	EO sterile, double lock, finger grip	\$0.50–\$0.70 (bulk)	Common in LMIC tenders
Local 3D-Print Designs	Open/research designs; rapid local manufacture; adaptable	Material = cents + sterility cost	QA, sterility, regulatory compliance define viability

Regulatory & Standards

- FDA: Umbilical occlusion device – Class I, 510(k) exempt (general controls). Example 510(k)s exist for branded clamps.
- QMS: ISO 13485; design controls (and US 21 CFR 820 where applicable).
- Biocompatibility: ISO 10993.1 plan (likely cytotoxicity, sensitization, irritation).
- Packaging/Sterility: ISO 11607.1/.2 sterile barrier systems; EtO/steam validation; shelf-life and labeling.

Verification & Validation Plan (Essentials)

- Bench occlusion/leak tests using simulated vessels at pressure; evaluate after cord shrink simulations. Tensile & latch strength; cyclic fatigue; drop testing; dimensional checks.
- Biocompatibility screening per ISO 10993; extractables/leachables as needed.
- Sterilization validation (EtO/steam) + post sterilization mechanical testing.
- Usability with clinicians; IFU clarity; compatibility with delayed clamping protocols.

Unit Economics (Small Batch Printing)

Material	PETG/PC filament ~8–12 g	\$0.05–\$0.15
Print & Postprocess	Amortized printer + labor	\$0.08–\$0.20
QA & Functional Test	Force/leak test jigs	\$0.05–\$0.10
Sterilization	Centralized EtO batch	\$0.15–\$0.30
Packaging/Labeling	Pouch + label + IFU	\$0.08–\$0.15
Total		\$0.41–\$0.90

References

UNICEF Data (2025): Neonatal mortality; Nigeria country profile.

WHO (2024): Newborn mortality fact sheet; delayed cord clamping guideline.

NEST360 / Rice 360 (2024–2025): Program resources; Neonatal Inpatient Dataset (NID).

FDA: 21 CFR; 510(k) examples for umbilical cord clamps; Biocompatibility guidance on ISO 10993-1.

ISO 13485 (QMS), ISO 10993 (biocompatibility), ISO 11607 (sterile packaging).

Market/pricing pages: Medline, Hollister, Angioplast, DeRoyal; 3D-print initiatives (Kenya, Haiti).