Appendix

Title:	**Essential Consumables Kit (Single Use, Sterile) Product Quality Specifications**
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USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
QUALITY ASSURANCE

1.0 KIT DESCRIPTION

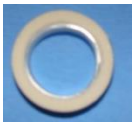
The Essential Consumables Kit (Single Use, Sterile) contains disposable (single use) consumables for use with the Instruments for Dorsal Slit Procedure Kit (Reusable, Non-Sterile). Items in the kit are conveniently provided in a multipurpose recyclable plastic tray. The kit is wrapped in surgical crepe paper (60 x 60 cm) and is sterilized by ethylene oxide in a 0.3µ sterilization indicator bag. The expiration date is indicated on the sterilization bag.

Item #	Component Name	Component Specifications	Quantity *(per kit)*	Picture *(for illustrative purposes only)*

1	Multipurpose Container Tray	• Stable recyclable tray composed of a virgin plastic (minimum 700 micron), with 4 compartments:
		  • Compartment 1 = 13 x 26 cm
		  • Compartment 2 = 5 x 8 cm
		  • Compartment 3 = 5 x 5 cm
		  • Compartment 4 = 5 x 13 cm
		• Total tray size: 26 x 18 cm
			1	

2	O-Drape	• Dimensions: 100 x 75 cm • Disposable • One side absorbent and one side impermeable; the two sides should be fused together and without lint *Note: The O-hole should be closer to the center, and the drape should be folded in such a way that the O-hole is visible with the impermeable side exposed without unfolding or touching the drape*	1	
3	Gauze, Plain	• Dimensions: 100 x 100 mm • 12 ply Also known as gauze swabs	20	
4	Paraffin Gauze Dressing	• Dimensions: 10 x 10 cm • 1 ply • Packaging: in foil pack Also known as Paranet gauze	1	
5	Syringe	• Size: 10 mL • Disposable	1	
6	Injection Needle, 21G	• Gauge: 21G • Length: 1.5 inch	1	
7	Injection Needle, 25G	• Gauge: 25G • Length: 1.5 inch	1	

Item #	Component Name	Component Specifications	Quantity *(per kit)*	Picture *(for illustrative purposes only)*
8	Suture	• Size: 4-0 • Suture length: 75 cm • Suture material: braided synthetic polyglactin 910 (e.g., Vicryl Rapide™) • Needle type: 3/8 circle reverse cutting • Needle length: 19 mm • Color: natural (undyed) • Packaging: individually packaged in sterile medical grade pack	2	
9	Surgical Gloves, Size 7	• Latex or nitrile • Size: 7 • Non-powdered • Packaging: individually packed in an ethylene oxide-penetrable envelope or pouch • Properly labeled with the size on the glove packaging or, alternatively, printed on the glove wrist and visible during kit opening • Sterile upon kit sterilization • Label accurately describes the product and includes a list of any body-contacting materials • Adequate stability data to support shelf life claims greater than 3 years • Manufacturer not listed in USFDA Import Alert 80-04	2 pairs	
10	Surgical Gloves, Size 7.5	• Latex or nitrile • Size: 7.5 • Non-powdered • Packaging: individually packed in an ethylene oxide-penetrable envelope or pouch • Properly labeled with the size on the glove packaging or, alternatively, printed on the glove wrist and visible during kit opening • Sterile upon kit sterilization • Label accurately describes the product and includes a list of any body-contacting materials • Adequate stability data to support shelf life claims greater than 3 years • Manufacturer not listed in USFDA Import Alert 80-04	1 pair	

Item #	Component Name	Component Specifications	Quantity *(per kit)*	Picture *(for illustrative purposes only)*
11	Surgical Gloves, Size 8	• Latex or nitrile • Size: 8 • Non-powdered • Packaging: individually packed in an ethylene oxide-penetrable envelope or pouch • Properly labeled with the size on the glove packaging or, alternatively, printed on the glove wrist and visible during kit opening • Sterile upon kit sterilization • Label accurately describes the product and includes a list of any body-contacting materials • Adequate stability data to support shelf life claims greater than 3 years • Manufacturer not listed in USFDA Import Alert 80-04	1 pair	
12	Apron, Disposable	• Material: plastic • Minimum thickness: 2 mil/50 micron	2	
13	Alcohol Swabs	• Dimensions: 1.25 x 2.5 inch • Saturated with 70% isopropyl alcohol • Disposable • Individually packaged	2	
14	Surgical Tape	• Type: surgical grade • Width: 12 mm • Length: 3 meters	1 roll	
15	Examination Gloves, Medium	• Latex or nitrile • Size: medium • Non-powdered • Properly labeled with the size on the glove packaging or, alternatively, printed on the glove wrist and visible during kit opening • Sterile upon kit sterilization • Label accurately describes the product and includes a list of any body-contacting materials • Adequate stability data to support shelf life claims greater than 3 years • Manufacturer not listed in USFDA Import Alert 80-04	1 pair	

Item #	Component Name	Component Specifications	Quantity *(per kit)*	Picture *(for illustrative purposes only)*
16	Examination Gloves, Large	• Latex or nitrile • Size: large • Non-powdered • Properly labeled with the size on the glove packaging or, alternatively, printed on the glove wrist and visible during kit opening • Sterile upon kit sterilization • Label accurately describes the product and includes a list of any body-contacting materials • Adequate stability data to support shelf life claims greater than 3 years • Manufacturer not listed in USFDA Import Alert 80-04	1 pair	
17	Paper Towels	• Four pieces Note: for drying clean hands during preparation	4 pieces	
18	Skin Marker	• Basic marker to be included in the pack • Does not have to be sterile prior to ethylene oxide sterilization	1	
Kit Packaging and Sterilization				
19	Surgical Crepe Paper	• Wrapping: surgical blue crepe paper • Dimensions: 60 x 60 cm	1	
20	Sterility Indicators	Kit must contain at least 3 ethylene oxide sterility indicators: • 1 x Class 1 chemical indicator tape • 2 x Class 4 chemical indicator strip or class 5 indicator	3	
21	Indicator Bag	• 0.3µ sterilization indicator bag used for kit ethylene oxide sterilization	1	

2.0 QUALITY STANDARDS

2.1 Manufacturers of surgical instruments shall be listed with the USFDA and shall provide evidence of established medical device registration with the USFDA, or be CE marked.

2.2 The following individual components (non-surgical instruments) shall have evidence of USFDA 510k and the manufacturer shall provide evidence of established medical device registration with the USFDA, or be CE marked (with notified body):

- Gauze, plain
- Paraffin gauze dressing
- Syringe

- Injection needles
- Suture
- Surgical gloves
- Alcohol swabs
- Examination gloves
- Sterility indicators

2.3 Syringes shall be compliant with the following applicable standards or their equivalent:

- ISO 7886-1:2017 Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use
- ISO 7886-3:2020 Sterile hypodermic syringes for single use -- Part 3: Auto-disabled syringes for fixed-dose immunization
- ISO 11608-1:2022 Needle-based injection systems for medical use -- Requirements and test methods -- Part 1: Needle-based injection systems
- ISO 11608-2:2012 Needle-based injection systems for medical use -- Requirements and test methods -- Part 2: Needles
- ISO 11608-3:2012 Needle based injection systems for medical use -- Requirements and test methods -- Part 3: Finished containers
- ISO 23908:2011 Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

2.4 Injection needles shall be compliant with the following applicable standards or their equivalent:

- ISO 6009:2016 Hypodermic needles for single use -- Colour coding for identification
- ISO 7864:2016 Sterile hypodermic needles for single use -- Requirements and test methods
- ISO 9626:2016 Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods
- ISO 23908:2011 Sharps injury protection -- Requirements and test methods -- Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling
- ASTM F3212-16 Standard Test Method for Coring Testing of Huber Needles

2.5 Sutures shall be compliant with the following applicable standards or their equivalent:

- USP 42-NF37:2019 Sutures - Diameter <861>
- USP 42-NF37:2019 Sutures - Needle Attachment <871>
- USP 42-NF37:2019 Tensile Strength <881>

2.6 Surgical gloves shall be compliant with the following applicable standards or their equivalent:

- ASTM D3577-19 Standard Specification for Rubber Surgical Gloves
  OR
- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
  OR
- European standards for both latex and nitrile medical gloves:
  - EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes; and
  - EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties; and
  - EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation; and

- EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

2.7 Examination gloves shall be compliant with the following applicable standards or their equivalent:

- ASTM D3578-19 Standard Specification for Rubber Examination Gloves
  OR
- ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application
  OR
- European standards for both latex and nitrile medical gloves:
  - EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes; and
  - EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties; and
  - EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation; and
  - EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination

2.8 Sterility indicators shall be compliant with the following applicable standards or their equivalent:

- ISO 15882:2008 Sterilization of health care products -- Chemical indicators -- Guidance for selection, use and interpretation of results
- ISO 11140-1:2014 Sterilization of health care products -- Chemical indicators -- Part 1: General requirements

2.9 Manufacturers of each individual component shall have evidence of ISO 9001:2015 Quality management systems -- Requirements, or ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes certification or an equivalent.

2.10 The Essential Consumables Kit (Single Use, Sterile) supplied shall be manufactured in accordance with ISO 11135-1:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices and ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes.

2.11 Supplier and kitting organizations must have a quality management system and be quality assured with certifications like ISO 9001:2015 Quality management systems -- Requirements, or ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes; or approved by a standards regulatory body in the country of the manufacturer, which bodies must be accredited by or affiliated with standards institutes like ISO with a copy of certification(s) included.

2.12 Sterilization organizations must have a quality management system and be quality assured with certifications like ISO 13485:2016 Medical devices -- Quality management systems -- Requirements for regulatory purposes and ISO 11135-1:2014 Sterilization of health-care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices.

2.13 No kit component shall be included in any active import alert or in violation of the USFDA's laws and regulations.

3.0 PACKING

3.1 The kit components should be packed based on the order of use during the procedure, with those items to be used first on top and items used last on the bottom. At a minimum, the first item (that

is, top component when the kit is opened) shall be the examination gloves, followed by the apron. The dressing and gauze should be on the bottom. This helps maintain the sterility of the kit as well as the sterile field throughout the procedure.

4.0 STERILIZATION ASSURANCE

4.1 The Essential Consumables Kit (Single Use, Sterile) shall have at least three (3) chemical indicators used to indicate kit sterility as follows:

- **Exterior indicator**: A sterility indicator is to be placed in a visible location on the exterior of the kit but inside the sterility indicator bag. This indicator may be a Class 1 chemical indicator tape, used to visually demonstrate the kit has been exposed to the sterilant.
- **Top indicator**: A sterility indicator strip shall be placed immediately on top of the kit components (i.e., on top of the examination gloves) as this allows the healthcare provider to immediately confirm sterility before beginning the procedure. This sterility indicator may be a Class 4 chemical indicator strip with multiple variable chemical indicators, or a Class 5 integrating indicator which reacts with all critical sterilization parameters.
- **Middle or bottom indicator**: A sterility indicator strip can be placed anywhere within the middle or bottom of the kit. This last chemical indicator is used to confirm that the ethylene oxide has penetrated to the most difficult to reach internal components. This sterility indicator may be a Class 4 chemical indicator strip with multiple variable chemical indicators, or a Class 5 integrating indicator which reacts with all critical sterilization parameters.

5.0 MARKING

5.1 Each kit and its individual components should use symbols according to ISO 15223-1:2021 Medical Devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements.

5.2 Single use instruments should be marked to indicate the instrument is not intended for reuse (i.e., symbols and/or marked by the words “single use” or ⊗).

6.0 LABELING

6.1 A master label (see Section 10) shall be attached to each kit, provided by the supplier, and shall be visible without opening the kit. At minimum, the following information shall be provided in the master label:

- Kit name
- Kit ID code
- List of contents and corresponding quantities for each component
- Storage conditions
- Lot/batch number
- Manufacture and expiration dates
- “Report Product Quality Complaints to USAID|GHSC-QA: ghscqa@fhi360.org or call +1-855-442-9482.”
- Symbols used according to ISO 15223-1:2021 Medical Devices -- Symbols to be used with information to be supplied by the manufacturer -- Part 1: General requirements (e.g., do not use if pack is opened or damaged)
- Supplier’s name, address, and contact information
- Kitting organization’s name, address, and contact information
- Sterilization organization’s name, address, and contact information

6.2 The Essential Consumables Kit (Single Use, Sterile) shall include an identification sticker attached to the master label. The identification sticker shall be a peelable adhesive sticker with the printed kit lot number. Identification stickers should be peeled from each kit and placed on the file of the patient undergoing the procedure for traceability purposes in case of recalls or quality concerns reported.

7.0 CARTON PACKAGING AND LABELING

7.1 The vendor shall supply the Essential Consumables Kit (Single Use, Sterile) in export cartons ensuring that the cartons adequately protect the kits while they are in transit, stored in warehouses, or on pharmacy shelves under conditions expected to prevail in the cooperating country(ies).

7.2 Each carton containing the Essential Consumables Kit (Single Use, Sterile) shall include the following minimum information in English (unless otherwise specified on the purchase order):

- "Essential Consumables Kit (Single Use, Sterile)" and kit description
- Manufacture and expiration dates
- Sterilization lot number
- Any other marking specified in the purchase order or by the procurement service agent

8.0 TRACEABILITY

8.1 The vendor is required to maintain traceability of the Essential Consumables Kit (Single Use, Sterile) at the component level, such that the vendor can trace each component lot of the kit to its manufacturer or supplier.

8.2 Production lots or batches of individual sterile components in each kit must be fully traceable to the sterilization cycle.

8.3 The supplier shall provide a certificate of conformance for the kit, signed by QA staff, for each lot procured.

9.0 SHELF LIFE

9.1 The Essential Consumables Kit (Single Use, Sterile) shall have a minimum shelf life of 24 months from the date of manufacture unless otherwise agreed upon in the subcontract between the procurement service agent and the supplier.

9.1.1 All items inside the kit must have an expiration date greater than 24 months from the date of manufacture.

9.1.2 The expiration date of individual items should be included when applicable (i.e., gloves, suture, injection needle, syringe, etc.).

9.1.3 The expiration date of a kit shall not be greater than the expiration date of the first component in the kit to expire.

9.1.4 The expiration dates of all kits in a sterilization lot shall be identical.

10.0 MASTER LABEL TEMPLATE

USAID VOLUNTARY MEDICAL MALE CIRCUMCISION KIT

[Kit Name]

Single Use, Sterile

[ID Code]

COMPONENT	QUANTITY

Store at a temperature below 30°C.
Store in a clean, dry, dust and lint-free area.

STERILE | EO

STERILE UNLESS PACK HAS BEEN DAMAGED OR OPENED

DO NOT USE IF PACK IS OPENED OR DAMAGED

Lot/Batch No.: _____
Mfg: _____
Exp: _____

Patient: _____
[Kit Name] — Single Use, Sterile
Lot/Batch No.: _____

PEEL TO OPEN

Report Product Quality Complaints to USAID|GHSC-QA: ghscqa@fhi360.org or call +1-855-442-9482

MANUFACTURED BY: _____

DISTRIBUTED BY: _____
ADDRESS: _____
EMAIL: _____
PHONE: _____

KITTED BY: _____
ADDRESS: _____
EMAIL: _____
PHONE: _____

STERILIZED BY: _____
ADDRESS: _____
EMAIL: _____
PHONE: _____

MALE CIRCUMCISION PROCEDURE KIT
(Forceps-Guided Procedure **SHOULD NOT BE USED** on clients 10-14 years of age)