Appendix

Title:	**Instruments for Forceps-Guided Procedure Kit (Reusable, Non-Sterile) Product Quality Specifications**
Document No:	QA.APP.KIT.VMMC-103.04
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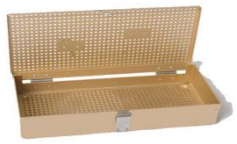
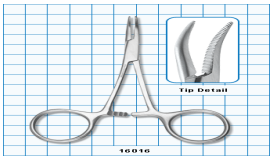
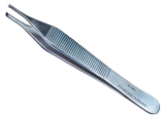
USAID GLOBAL HEALTH SUPPLY CHAIN PROGRAM
QUALITY ASSURANCE

1.0 KIT DESCRIPTION

The Instruments for Forceps-Guided Procedure Kit (Reusable, Non-Sterile) contains a set of reusable metal surgical instruments.

Item #	Component Name	Component Specifications	Quantity *(per kit)*	Picture *(for illustrative purposes only)*
1	Autoclave Storage Box	Estimated dimensions range: 10 x 3 x 2 - 10 x 5 x 2 inch (L x W x H)	1	
Reusable Surgical Instruments – Packed into Autoclave Storage Box				
2	Needle Holder	• Total length: 12-14 cm • Working surface: 20 mm • Serrated jaws Example: Baumgartner needle holder	1	
3	Suture Scissors	• Total length: 12-15 cm • Sharp enough to cut tissue Example: straight Mayo suture scissors	1	
4	Mosquito Clamp, Straight	• Total length: 12-14 cm • Working surface: 20-30 mm Also known as "snaps," mosquito forceps, hemostatic forceps Example: Halstead straight mosquito	4	
5	Mosquito Clamp, Curved	• Total length: 12-14 cm • Working surface: 20-30 mm Also known as "snaps," mosquito forceps, hemostatic forceps Example: Halstead curved mosquito	1	
6	Forceps, Hemostatic Cross Clamp	• Total length: 20 cm • Working surface: 64 mm Also known as hemostatic circumcision forceps	1	
7	Metal Tissue Forceps	• Total length: 12 cm • Tip: 1 x 2 tooth – delicate tips Also known as Adson forceps	1	
Reusable kits need not be sterile. The master label shall include the following text: "NON-STERILE MUST STERILIZE/AUTOCLAVE BEFORE USE"				

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 Surgical components shall be made of martensitic stainless steel (quenched, magnetic steel) and meet ISO 7153-1:2016 Surgical instruments -- Materials -- Part 1: Metals and ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure.

2.3 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.

2.4 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 be 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.

2.5 No kit component shall be included in any active import alert or in violation of the USFDA's laws and regulations. Steel medical instruments (stainless or non-stainless, for surgical use or non-surgical use, and single use or multiple use) from Pakistan shall have met the criteria for exclusion from Detention Without Physical Examination (DWPE) under Import Alert 76-01 (a.k.a. Green List).

3.0 PACKING

3.1 Instruments shall be packaged in such a way to protect them from damage during transit that could impair the instruments' function or shorten the instruments' useful life.

4.0 STERILIZATION ASSURANCE

4.1 Reusable kits are not supplied sterile.

5.0 MARKING

5.1 As applicable, kits and their 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.

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, non-sterile)
- Supplier's name, address, and contact information
- Kitting organization's name, address, and contact information
- Maximum number of sterilization cycles advised by the supplier*
- "NON-STERILE MUST STERILIZE/AUTOCLAVE BEFORE USE"

* Suppliers are requested to provide guidance on the number of times components may be reused based on applicable ISO standards (ISO 13402:1995 Surgical and dental hand instruments -- Determination of resistance against autoclaving, corrosion and thermal exposure; ISO 7151:1988 Surgical instruments -- Non-cutting, articulated instruments -- General requirements and test methods; ISO 7153-1:2016 Surgical instruments -- Materials -- Part 1: Metals; and/or ISO 7741:1986 Instruments for surgery -- Scissors and shears -- General requirements and test methods).

7.0 CARTON PACKAGING AND LABELING

7.1 The vendor shall supply the Instruments for Forceps-Guided Procedure Kit (Reusable, Non-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 of Instruments for Forceps-Guided Procedure Kit (Reusable, Non-Sterile) shall include the following minimum information in English (unless otherwise specified on the purchase order):

- "Instruments for Forceps-Guided Procedure Kit (Reusable, Non-Sterile)" and kit description
- Manufacture and expiration dates
- 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 Instruments for Forceps-Guided Procedure Kit (Reusable, Non-Sterile) at the component level, such that the vendor can trace each component lot of the kit to its manufacturer or supplier.

8.2 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 Instruments for Forceps-Guided Procedure Kit (Reusable, Non-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 a kit shall not be greater than the expiration date of the first component in the kit to expire.

10.0 MASTER LABEL TEMPLATE

USAID VOLUNTARY MEDICAL MALE CIRCUMCISION KIT

[Kit Name]

Reusable, Non-Sterile

[ID Code]

COMPONENT	QUANTITY

Store in a clean, dry, dust and lint-free area.

NON-STERILE

MUST STERILIZE/AUTOCLAVE BEFORE USE

MAX no. of sterilization cycles advised:

DO NOT USE IF PACK IS OPENED OR DAMAGED

Lot/Batch No.: _____

Mfg: _____

Exp: _____

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: _____

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