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Interagency List of Essential Medical Devices for Reproductive Health

World Health Organization

John Snow Inc.

PATH

Population Action International

United Nations Population Fund

World Bank

In collaboration with the United Nations Children's Fund

Contents

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Background

Medical devices are essential to the provision of quality reproductive health (RH) services. Rational selection of medical devices is a crucial component in ensuring improved access to reproductive health commodities, followed by efficient procurement, logistical systems, rational use and demand which are equally important.

A review of existing United Nations (UN) lists of essential medicines and medical devices, including (1) *The draft UNFPA/WHO Essential Drugs and Other Commodities for Reproductive Health Services List (2003)* and (2) *The Interagency UNFPA/UNAIDS/WHO Reproductive Health Medicines and Commodities List* reported a lack of consensus among various UN agencies on essential medicines and medical devices for RH. Lack of consistent advice to countries on selection of RH medicines and medical devices may hamper access to them. Thus, this review was the catalyst towards the development of one interagency list of essential medicines for RH and one interagency list for essential medical devices for RH.

In 2005, the *Interagency List of Essential Medicines for Reproductive Health* developed by WHO in collaboration with partners was endorsed by major international organizations and agencies. In addition, the interagency working group for the selection of essential commodities for reproductive health agreed to work towards a harmonized list of essential medical devices for RH.

As defined by the Global Harmonization Task Force (GHTF), **medical device** means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing information for medical or diagnostic purposes by means of *in vitro*
- examination of specimens derived from the human body, and;

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

Objective of the Interagency List of Essential Medical Devices for Reproductive Health

This interagency list is a tool to support planning for the selection, quality assurance and procurement of medical devices to implement the Maternal and Newborn Health (MNH) interventions, which are defined as the "Essential care to women and their newborn during pregnancy, childbirth and postnatal period: up to six weeks after delivery." The objective of this list is to propose an international consensus on a rational selection of essential medical devices for reproductive health according to their public health relevance on the basis of evidence regarding, efficacy, safety and cost effectiveness.

Process

The Interagency List of Essential Medical Devices for Reproductive Health was developed by WHO in collaboration with UNICEF and UNFPA and major international and nongovernmental organizations active in the field of reproductive health. In 2004 and 2005, several interagency meetings were held to discuss the discrepancy medical devices existing among the various lists. During these consultations, the decision was taken to develop a common list of devices per category of products and not per range of clinical interventions, to avoid redundancy. Agreements were reached regarding the range of MNH interventions to be considered, the products nomenclature, the products classification to be used and the addition of technical specifications per product listed.

The criterion for a device to be included in the interagency list is to be identified as essential to maternal and newborn health interventions according to procedures described in the WHO standard treatment guidelines. (See Annex 1 for a list of interventions).

Medical devices requested for laboratory (including diagnostic tests) and blood transfusion services are not included in the list.

Products nomenclature

The nomenclature for the Interagency List of Essential Medical Devices for Reproductive Health is based on the existing United Nations Common Coding System (UNCCS) and the UNICEF products database for the classification of products groups.

All products from this list are identified with a generic, short description with a maximum of 50 characters, except for the sutures. The complete technical specifications of the products are based on the UNICEF standard products.

Note: this nomenclature was used for the elaboration of the interagency guideline: "Emergency Relief Items - Volume 2 (July 1999)", related to medical devices, medicines and emergency health kits.

Products classification

The list of products is divided into three major categories and each category can be divided into sub-groups:

Categories	Sub-groups
Medical Devices - Renewable/Consumables	• Renewable plastic goods • Injection devices • Dressing supplies • Surgical sutures • Clothing and accessories • Medical stationery
Medical Devices - Equipment	• Anthropometric equipment • Medical diagnostic equipment • Medical utensils • Sterilization equipment • Hospital equipment • Anaesthesia/resuscitation equipment • Surgical instruments sets (UNFPA and UNICEF surgical instruments sets)
Medical Devices - Medical Kits	• The list is composed of the medical kits developed by UNICEF and the Inter-Agency Reproductive Health Kits.

This products classification system facilitates rapid research about the needed medical devices. It is also a guarantee of maintaining coherence in the whole list and obtaining a clear overview of what is needed to set up a reproductive health service.

The list of products is specified by two levels of care: the first level of MNH care and the referral level. The first level of care for MNH includes normal care that should be offered to all women, including pregnant women, and babies, and the initial management of complications. The secondary level of care is the referral level where complications are managed (e.g. the district hospital).

Ten **special notes** have been added as Annex 2 to the list to complement technical information and improve use of the list. Notes were developed in the following areas:

- Units measure and biomaterials used for medical devices
- Packaging and labelling
- Injection safety
- Health-care waste management
- Surgical sutures
- Standard precaution for health workers
- Wearing protective equipment
- Textiles used for linen and clothing
- Sterilization of medical devices
- Stainless steel for surgical instruments.

Products technical specifications

Technical specifications per generic product were developed in collaboration with UNICEF and UNFPA. Each product specification is a set of technical characteristics describing the device. The aim is to support procurement officers, pharmacists, project managers in selecting, pre-qualifying and procuring these medical devices.

These product specifications are available on the web site at:
http://www.supply.unicef.dk/catalogue/medical.htm

The quantification of medical devices needed per intervention will be based on assessments at national level and will systematically take into consideration the following criteria:

- ***The health system:*** policies and protocols.
- ***The health facility:*** capacity, activities and organization.
- ***The existing replenishment/inventory system for medical devices:*** renewable/consumable and equipment.

Next steps: request for comments and suggestions

The WHO Department of Essential Medicines and Pharmaceutical Policy, along with the other organizations involved, plans to update the Interagency List of Essential Medical Devices for Reproductive Health every two years. Meanwhile, any comments or suggestions regarding the list can be addressed to the Department of Essential Medicines and Pharmaceutical Policy, World Health Organization, 20 Avenue Appia, CH-1211 Geneva 27, Switzerland, or email: par@who.int

Additional references

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Interagency List of Essential Medical Devices for Reproductive Health

Structure of the list

Medical Devices - Renewable/Consumables

1 Renewable plastic goods
- 1.1 Tube/catheter/drain
- 1.2 Gloves
- 1.3 Miscellaneous renewable plastic

2 Injection devices
- 2.1 Needles/cannulae
- 2.2 Syringes - immunization
- 2.3 Syringes - others
- 2.4 Sharps waste disposal
- 2.5 Miscellaneous injection devices

3 Dressing supplies
- 3.1 Compress/bandage/tape
- 3.2 Miscellaneous dressing

4 Surgical sutures
- 4.1 Sutures, absorbable
- 4.2 Sutures, non-absorbable

5 Clothing and accessories

6 Medical stationery

Medical Devices - Equipment

1 Anthropometric equipment

2 Medical Diagnostic equipment
- 2.1 Electrical equipment (*220V)
- 2.2 Other medical diagnostic equipment

3 Medical utensils
- 3.1 Steel utensils
- 3.2 Plastic utensils

4 Sterilization equipment
- 4.1 Sterilizers
- 4.2 Containers
- 4.3 Other sterilization equipment

5 Hospital equipment

- 5.1 Electrical equipment (*220V)
- 5.2 Others hospital equipment & furniture
- 5.3 Miscellaneous others equipment

6 Anaesthesia/Resuscitation equipment

- 6.1 Electrical equipment (*220V)
- 6.2 Other anaesthesia equipment

Medical Devices - Equipment: surgical instruments sets

7 Surgical instruments sets

- 7.1 UNICEF surgical instruments sets
- 7.2 UNFPA surgical instruments sets

Medical Devices - Medical kits

1 UNICEF Kits
2 Inter-Agency Reproductive Health Kits for crisis situations

Medical Devices - Renewable/Consumables

"Special note" on units measure and biomaterials used for medical devices

Item line	Product classification/Short description	First-level MNH care (services provided close to clients)	Referral level (back-up care at sec. health-care level)
1	**Renewable Plastic Goods**		
1.1	**Tube/catheter/drain**		
	Catheter, urethral, (size:CH), sterile, single use		
1.1.1	Catheter,urethral,CH12,ster,s.u.	X	X
1.1.2	Catheter,urethral,CH14,ster,s.u.	X	X
	Catheter, Foley, (size:CH), sterile, single use		
1.1.3	Catheter,Foley,CH10,ster,s.u.		X
1.1.4	Catheter,Foley,CH12,ster,s.u.		X
1.1.5	Catheter,Foley,CH14,ster,s.u.		X
1.1.6	Catheter,Foley,CH18,ster,s.u.		X
	Syringe, feeding, (connector tip), (capacity: ml), sterile, single use		
1.1.7	Syringe,feeding,catheter tip,50ml,ster,s.u.	X	X
1.1.8	Syringe,feeding,luer tip,50ml,ster,s.u.		X
1.1.9	Extractor,mucus,20ml,ster,s.u.	X	X
	Tube, aspirating/feeding, (size:CH), (Length: cm), conical tip, sterile, single use		
1.1.10	Tube,asp/feed,CH06,L125cm,conical tip,ster,s.u.		X
1.1.11	Tube,asp/feed,CH08,L125cm,conical tip,ster,s.u.		X
1.1.12	Tube,asp/feed,CH12,L125cm,conical tip,ster,s.u.		X
1.1.13	Tube,asp/feed,CH16,L125cm,conical tip,ster,s.u.		X
	Tube, feeding, (size: CH), (length: cm), luer tip, sterile, single use		
1.1.14	Tube,feeding,CH05,L40cm,luer tip,ster,s.u.		X
1.1.15	Tube,feeding,CH08,L40cm,luer tip,ster,s.u.		X
	Tube, suction, (size: CH), (length: cm), conical tip, sterile, single use		
1.1.16	Tube,suction,CH08,L50cm,conical tip,ster,s.u.	X	X
1.1.17	Tube,suction,CH10,L50cm,conical tip,ster,s.u.	X	X
1.1.18	Tube,suction,CH14,L50cm,conical tip,ster,s.u.	X	X
1.1.19	Tube,suction,CH16,L50cm,conical tip,ster,s.u.	X	X
	Airway Guedel		
1.1.20	Airway, Guedel, translucent, size 00	X	X
1.1.21	Airway, Guedel, translucent, size 0	X	X
1.1.22	Airway, Guedel, translucent, size 1	X	X
1.1.23	Airway, Guedel, translucent, size 2	X	X
1.1.24	Airway, Guedel, translucent, size 3	X	X
1.1.25	Airway, Guedel, translucent, size 4	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (back-up care at sec. health-care level)
	Tube, endotracheal,(size: diam int.), without cuff, sterile, single use		
1.1.26	Tube,endotrach,2.5, w/o cuff,ster,s.u.		X
1.1.27	Tube,endotrach,3, w/o cuff,ster,s.u.		X
1.1.28	Tube,endotrach,3.5, w/o cuff,ster,s.u.		X
	Tube, endotracheal,(size: diam int.), with cuff, sterile, single use		
1.1.28	Tube,endotrach,6.5, w/cuff,ster,s.u.		X
1.1.29	Tube,endotrach,7, w/cuff,ster,s.u.		X
1.1.30	Tube,endotrach,7.5, w/cuff,ster,s.u.		X
1.1.31	Tube,endotrach,8, w/cuff,ster,s.u.		X
	Cannula, nasal, Oxygen, 2 prongs + tube, single use		
1.1.32	Cannula,nasal,Oxygen,adult,2 prongs + tube, s.u.		X
1.1.33	Cannula,nasal,Oxygen,child,2 prongs + tube,s.u.		X
1.1.34	Cannula,nasal,Oxygen,neonate,2 prongs + tube,s.u.		X
1.2	**Gloves**		
	Gloves, examination, (material), (size), single use		
1.2.1	Gloves,exam,latex,small,s.u.	X	X
1.2.2	Gloves,exam,latex,medium,s.u.	X	X
1.2.3	Gloves,exam,latex,large,s.u.	X	X
	Gloves, gynaecological, (size: n0), sterile, single use		
1.2.4	Gloves,gynaeco,small,ster,s.u.,pair	X	X
1.2.5	Gloves,gynaeco,medium,ster,s.u.,pair	X	X
1.2.6	Gloves,gynaeco,large,ster,s.u.,pair	X	X
	Gloves, surgical, (size: n0), sterile, single use		
1.2.7	Gloves,surg,6.5,ster,s.u.,pair	X	X
1.2.8	Gloves,surg,7,ster,s.u.,pair	X	X
1.2.9	Gloves,surg,7.5,ster,s.u.,pair	X	X
1.2.10	Gloves,surg,8,ster,s.u.,pair	X	X
1.2.11	Gloves,surg,8.5,ster,s.u.,pair	X	X
1.3	**Miscellaneous renewable plastic**		
1.3.1	Bag (envelope),plastic,for drugs, approx.10x15cm	X	X
1.3.2	Bag,urine,collecting,2000ml		X
2	**Injection devices**		
	"Special note" on injection safety		
2.1	**Needles / cannulae** (1)		
	Cannula, Intra Venous short, (size:G), sterile, single use		
2.1.1	Cannula,IV short,16G,ster,s.u.	X	X
2.1.2	Cannula,IV short,18G,ster,s.u.	X	X
2.1.3	Cannula,IV short,20G,ster,s.u.	X	X
2.1.4	Cannula,IV short,22G,ster,s.u.	X	X
2.1.5	Cannula,IV short,24G,ster,s.u.	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (back-up care at sec. health-care level)
	Needle, luer, (size:G & mm), sterile, single use		
2.1.6	Needle,luer,19G(1.1x40mm),ster,s.u.	X	X
2.1.7	Needle,luer,21G(0.8x40mm),ster,s.u.	X	X
2.1.8	Needle,luer,23G(0.6x25mm),ster,s.u.	X	X
2.1.9	Needle,luer,25G(0.5x16mm),ster,s.u.	X	X
	Needle, scalp vein, (size:G), sterile, single use		
2.1.10	Needle,scalp vein,21G,ster,s.u.	X	X
2.1.11	Needle,scalp vein,25G,ster,s.u.	X	X
	Needle, spinal, (size:G & mm), sterile, single use		
2.1.12	Needle,spinal,20G(0.9x90mm),ster,s.u.		X
2.1.13	Needle,spinal,22G(0.7x90mm),ster,s.u.		X
2.2	**Syringes - Immunization**		
	Syringe, auto-disable		
2.2.1	Syringe, auto-disable, 0.5 ml, ster	X	X
2.2.2	Syringe, auto-disable, 0.05 ml, ster	X	X
2.3	**Syringes - Others** (1)		
	Syringe, luer, (capacity:ml), sterile, single use		
2.3.1	Syringe,luer,1ml,ster,s.u.	X	X
2.3.2	Syringe,luer,2ml,ster,s.u.	X	X
2.3.3	Syringe,luer,5ml,ster,s.u.	X	X
2.3.4	Syringe,luer,10ml,ster,s.u.	X	X
2.3.5	Syringe,luer,20ml,ster,s.u.	X	X
	(1) RPF (reuse-prevention feature) injection devices should be considered.		
2.4	**Sharps waste disposal** **"Special note" on health-care waste management**		
2.4.1	Safety box, f.used syrgs/ndls, 5L	X	X
2.5	**Miscellaneous injection devices**		
2.5.1	Infusion giving set,ster,s.u.	X	X
	Note: Infusion giving set must be packed/delivered with Infusion (Interagency recommendation)		
2.5.2	Infusion giving set, burette 100-150ml,ster,s.u.	X	X
3	**Dressing supplies**		
3.1	**Compress / bandage / tape**		
	Compress / bandage / tape,(material), (size) (presentation)		
3.1.1	Bandage,elastic,7.5cmx5m,roll	X	X
3.1.2	Bandage,gauze,5cmx5m,roll	X	X
3.1.3	Bandage,gauze,8cmx4m,roll	X	X
3.1.4	Bandage,tricot,tubular,5cmx25m,roll		X
3.1.5	Compress,gauze,10x10cm,non-sterile	X	X
3.1.6	Compress,gauze,10x10cm,sterile,s.u.	X	X
3.1.7	Gauze,roll,90cmx100m,non-sterile	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (back-up care at sec. health-care level)
3.1.8	Tape,adhesive,zinc oxide,2.5cmx5m	X	X
3.1.9	Tape,adhesive,zinc oxide,perforated,10cmx5m		X
3.1.10	Tape,umbilical,3mmx50m,non-sterile	X	X
3.2	**Miscellaneous dressing**		
3.2.1	Blanket,survival,approx.220x140cm,non-ster	X	X
3.2.2	Clamp,umbilical,sterile,s.u.		X
3.2.3	Cotton wool,500g,roll,non-ster	X	X
3.2.4	Soap,toilet,bar,approx.110g,wrapped	X	X
4	**Surgical sutures**		
	"Special notes" on surgical sutures		
4.1	**Sutures, absorbable**		
	Sutures, (type of thread), (Decimal gauge of thread), needle (shape) (length) (point),sterile, single use		
4.1.1	Suture,synthetic,absorbable,DEC1(5/0),need 1/2,18mm,round,ster,s.u.		X
4.1.2	Suture,synthetic,absorbable,DEC2(3/0),need 3/8 18mm,round,ster,s.u.		X
4.1.3	Suture,synthetic,absorbable,DEC2(3/0),need 3/8,26mm,triangular,ster,s.u.	X	X
4.1.4	Suture,synthetic,absorbable,DEC3(2/0),need 1/2 30mm,round,ster,s.u.		X
4.1.5	Suture,synthetic,absorbable,DEC3(2/0),need 3/8 50mm,round,ster,s.u.	X	X
4.1.6	Suture,synthetic,absorbable,DEC4(1),need 3/8 36mm,triangularster,s.u.		X
4.2	**Sutures, non-absorbable**		
	Sutures, (type of thread), (decimal gauge of thread), needle, (shape) (length) (point),sterile, single use		
4.2.1	Suture,synthetic,non-absorbable,DEC2(3/0),need 3/8 13mm,triangular,ster,s.u.		X
4.2.2	Suture,synthetic,non-absorbable,DEC3(2/0),need 3/8 30mm,triangular,ster,s.u.	X	X
5	**Clothing and accessories.**		
	"Special note" on standard precautions for health workers & "Special note" on wearing protective equipment		
5.1	Apron,protection,plastic,disposable	X	X
5.2	Apron,protection,plastic,reusable	X	X
5.3	Drawsheet,plastic,approx. 90x180cm	X	X
5.4	Glasses,safety, regular size, disposable	X	X
5.5	Mask,surgical,s.u.	X	X
	Others: Medical clothing / linen		
	"Special note" on textiles used for linen and clothing		
5.6	Cap, surgical, non-woven	X	X
5.7	Clogs, plastic	X	X
5.8	Coat, medical, woven, white	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (back-up care at sec. health-care level)
5.9	Drape, surgical woven	X	X
5.10.	Gown, patient, woven	X	X
5.11	Gown, surgical, woven	X	X
5.12	Trousers, surgical, woven	X	X
5.13	Tunic, surgical, woven	X	X
6	**Medical stationery**		
6.1	Bag, plastic,for health card,11x25cm	X	X
6.2	Health card	X	X
6.3	Referral record	X	X
6.4	Feedback record	X	X
6.5	Labour record	X	X
6.6	Partograph	X	X
6.7	Postpartum record	X	X
6.8	Intern. form of medical certificate of death cause	X	X

Medical Devices - Equipment

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (Back-up care at sec. health-care level)
1	**Anthropometric Equipment**		
1.1	Bracelet, identification newborn	X	X
1.2	Height measuring instrument (0-2m)	X	X
1.3	Scale,adult/infant, electronic,150kgx100g	X	X
1.4	Scale,adult, mechanical,150 kg x 500 g	X	X
1.5	Scale,infant, clinic,metric 16kgx10g	X	X
1.6	Scale,infant, spring,5kgx25g, w/slings	X	X
2	**Medical Diagnostic Equipment**		
2.1	**Electrical equipment (*220V)**		
2.1.1	Doppler,fetal heart detector,w/access	X	X
2.1.2	Scanner,ultrasound,w/access		X
2.2	**Other medical diagnostic equipment**		
2.2.1	Flashlight,pre-focused	X	X
2.2.3	Tape,measuring,vinyl-coated,1.5m	X	X
2.2.4	Thermometer,clinical,digital 32-43C	X	X
2.2.5	Timer,respiration for ARI	X	X
2.2.6	Tongue depressor,wooden,s.u.	X	X
2.2.7	Tourniquet,rubber,approx.75cm	X	X
2.2.8	Sphygmomanometer,(adult),aneroid	X	X
2.2.9	Sphygmomanometer,(child),aneroid	X	X
2.2.10.	Stethoscope,binaural,complete	X	X
2.2.11	Stethoscope,fetal, monaural	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (Back-up care at sec. health-care level)
3	**Medical Utensils**		
3.1	**Steel utensils**		
3.1.1	Basin,kidney,stainless steel,approx.825ml	X	X
3.1.2	Bowl,round,stainless steel,approx.4L	X	X
3.1.3	Bowl,stainless steel,approx.180ml	X	X
3.1.4	Bowl,stainless steel,approx.600ml	X	X
3.1.5	Tray,dressing,stainless steel,approx.300x200x30mm	X	X
3.1.6	Tray,instruments,stainless steel,approx.480x330x20mm	X	X
3.1.7	Tray,instruments,stainless steel,approx.320x200x80mm,w/cover	X	X
3.1.8	Razor blades,double-edged, s.u./PAC-5	X	X
3.1.9	Razor,safety,metal,3-piece	X	X
3.1.10	Razor, single edge, plastic, s.u.	X	X
3.1.11	Receptacle,waste,stainless steel,pedal action,approx.21L	X	X
3.2	**Plastic utensils**		
3.2.1	Basin,kidney,polypropylene,approx.475ml	X	X
3.2.2	Bedpan,polypropylene,adult	X	X
3.2.3	Bottle,plastic,approx.250ml,wash bottle	X	X
3.2.4	Bottle,plastic,approx.1L,w/screw cap	X	X
3.2.5	Bowl,round,polypropylene,8L	X	X
3.2.6	Brush,hand,scrubbing,plastic	X	X
3.2.7	Jar,forceps,polypropylene,approx.180mm,w/o cover	X	X
3.2.8	Jar,thermometer,polypropylene,approx.110mm,w/o cover	X	X
3.2.9	Jug,measuring,plastic,approx.1L	X	X
3.2.10	Receptacle,waste,plastic,approx.13L, w/lid	X	X
4	**Sterilization Equipment** **"Special notes" on sterilization of reusable medical devices**		
4.1	**Sterilizers**		
	Electrical equipment (*220V)		
4.1.1	Sterilizer,steam,approx.40L,w/access	X	X
4.1.2	Sterilizer,steam,approx.100L,w/access		X
	Others		
4.1.3	Sterilizer,steam,approx.24L,w/access	X	X
4.1.4	Sterilizer,steam,approx.39L,w/access	X	X
4.2	**Containers**		
4.2.1	Basket,sterilizing, approx.120x250x60mm	X	X
4.2.2	Basket,sterilizing,approx. 240x250x60mm		X
4.2.3	Drum,sterilizing,approx.165mm diam	X	X
4.2.4	Drum,sterilizing,approx.260mm diam	X	X
4.2.5	Drum,sterilizing,approx.290mm diam	X	X
4.2.6	Drum,sterilizing,approx.340mm diam	X	X
4.3	**Other sterilization equipment**		
4.3.1	Indicator,TST control spot	X	X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (Back-up care at sec. health-care level)
4.3.2	Papersheet,crepe,for sterilization pack	X	X
4.3.3	Stove,kerosene,single-burner,pressure	X	X
4.3.4	Tape, adhesive, for sterilization pack	X	X
4.3.5	Timer,60 min	X	X
5	**Hospital Equipment**		
5.1	**Electrical equipment (*220V)**		
5.1.1	Electrosurgical unit,w/access		X
5.1.2	Light,examination,mobile,w/access	X	X
5.1.3	Light,Oper.theatre,mobile,w/access		X
5.1.4	Light, Oper. theatre, ceiling,w/access		X
5.1.5	Pump,suction,portable,1 bottle,w/access	X	X
5.1.6	Pump,suction,surgical,2 bottles,w/access		X
5.2	**Other hospital equipment & furniture**		
5.2.1	Bed,hospital,standard,w/mattress	X	X
5.2.2	Bed,hospital,ICU,w/mattress		X
5.2.3	Bed,labour/delivery,w/access	X	X
5.2.4	Bedscreen,hospital,on castors	X	X
5.2.5	Bucket,kick,stainless steel,on castors	X	X
5.2.6	Cabinet,bedside,standard	X	X
5.2.7	Cabinet,instruments,double door	X	X
5.2.8	Cabinet,medicine,double door	X	X
5.2.9	Cot,baby,hospital,w/bassinet,on castors	X	X
5.2.10	Footstool,two steps	X	X
5.2.11	Stand,infusion,double hook,on castors	X	X
5.2.12	Stand,single bowl,on castors	X	X
5.2.13	Stool,adjustable,on castors	X	X
5.2.14	Stretcher,foldable	X	X
5.2.15	Stretcher,patient,w/side rails	X	X
5.2.16	Table,baby dressing	X	X
5.2.17	Table,examination	X	X
5.2.18	Table,instr,Mayo type,stainless steel,on castors	X	X
5.2.19	Table,instr,stainless steel,2 trays,on castors	X	X
5.2.20	Table,gynaeco,delivery,w/access	X	X
5.2.21	Table,Oper.theatre,w/access.		X
5.2.22	Trolley,dressing,stainless steel,2 trays	X	X
5.2.23	Trolley,emergency,w/drawers	X	X
5.2.24	Trolley,soiled linen	X	X
5.2.25	Wheelchair, adult	X	X
5.3	**Miscellaneous other equipment**		
5.3.1	Vacuum extractor,Bird,manual,complete.set		X
5.3.2	Pump,breast,manual,w/access		X
6	**Anaesthesia / Resuscitation Equipment**		
6.1	**Electrical equipment (*220V)**		
6.1.1	Anaesthesia system, free-standing,w/access		X
6.1.2	Incubator,newborn,automatic,w/access		X
6.1.3	Monitor,patient,portable,w/access		X
6.1.4	Nebulizer,atomizer,w/elec.compressor/SET		X

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (Back-up care at sec. health-care level)
6.1.5	Oxygen concentrator/SET		X
6.1.6	Phototherapy unit, w/access		X
6.1.7	Pulse oximeter,portable, w/access		X
6.1.8	Pump,infusion,w/access		X
6.1.9	Table,resusc,newborn,w/access		X
6.1.10	Ventilator, resuscitation (adult-child), w/ access		X
6.1.11	Warmer,baby,electric/SET	X	X
6.2	**Other anaesthesia equipment**		
6.2.1	Laryngoscope,adult/child,set		X
6.2.2	Forceps Magill, adult		X
6.2.3	Forceps Magill, child		X
6.2.4	Pump,suction,foot-operated	X	X
6.2.5	Resuscitator,hand-operated,adult,set	X	X
6.2.6	Resuscitator,hand-operated,infant/child,set	X	X
Medical Devices - Equipment: Surgical instruments sets			
	"Special note" on surgical instruments stainless steel		
7	**Surgical Instruments Sets**		
7.1	**UNICEF surgical instruments sets**		
7.1.1	Surg.inst.,abdominal /SET		X
7.1.2	Surg.inst.,basic surgery /SET		X
7.1.3	Surg.inst.,curettage /SET		X
7.1.4	Surg.inst.,delivery /SET	X	X
7.1.5	Surg.inst.,dressing /SET	X	X
7.1.6	Surg.inst.,embryotomy /SET		
7.1.7	Surg.inst.,exam/sut,vaginal/cervical/SET		X
7.1.8	Surg.inst.,suture /SET	X	X
7.2	**UNFPA surgical instruments sets**		
7.2.1	Surg.inst.,abdominal tubal ligation/SET		X
7.2.2	Surg.inst.,IUD insertion & removal/SET	X	X
7.2.3	Surg.inst.,subdermal implant insertion & removal/SET	X	X
7.2.4	Surg.inst.,laparoscopy/SET		X
7.2.5	Surg.inst.,minilaparotomy/SET		X
7.2.6	Surg.inst.,non scalpel vasectomy/SET		X
7.2.7	Surg.inst.,vasectomy/SET		X
7.2.8	Manual Vacuum Aspiration instrument,w/access/SET	X	X

Medical Devices - Medical kits

Item line	Product classification / Short description	First-level MNH care (services provided close to clients)	Referral level (Back-up care at sec. health-care level)
	Medical kits		
1	**UNICEF Kits**		
	http://www.supply.unicef.dk/Catalogue/		
	Technical Bulletin No.4 - Midwifery Kit, Complete		
	Technical Bulletin No.5 - Obstetric, Surgical Kit, Complete		
1.1	Midwifery kit,1-drugs	X	X
1.2	Midwifery kit,2-equipment	X	X
1.3	Midwifery kit,3-renewable	X	X
1.4	Midwifery kit, supplementary 1a-drugs	X	X
1.5	Obstetric,surgical kit,suppl.1-drugs		X
1.6	Obstetric,surgical kit,suppl.2-equipment		X
1.7	Obstetric,surgical kit,suppl.3-renewable		X
1.8	Obstetric,surgical kit,suppl.1a-drugs		X
1.9	Resuscitation kit,basic	X	X
1.10.	Sterilization, kit C	X	X
2	**Inter-Agency Reproductive Health Kits for Crisis Situations**		
2.1	Kit 0: Administration kit		
2.2	Kit 1: Condom kit: Part A (male) and B (female)		
2.3	Kit 2: Clean Delivery kit (individual): Part A (mother) and B (birth attendant)		
2.4	Kit 3: Rape Treatment kit		
2.5	Kit 4: Oral and Injectable Contraception		
2.6	Kit 5: Treatment of Sexually Transmitted Infections		
2.7	Kit 6: Delivery kit (Health Facility)		
2.8	Kit 7: Intra Uterine Device		
2.9	Kit 8: Management of Complications of Abortions kit		
2.10.	Kit 9: Suture of Tears (vaginal and cervical) and Vaginal Examination kit		
2.11	Kit 10: Vacuum Extraction for Delivery (Manual) kit		
2.12	Kit 11: Referral level kit for Reproductive Health		
2.12.A	Part A: Reusable equipment		
2.12.B	Part B: Drugs and disposable equipment		
2.13	Kit 12: Blood Transfusion kit		

Annex 1: Integrated Management of Pregnancy and Childbirth (IMPAC)

	First-level MNH care (services provided close to clients)		Back-up care at sec. health-care level
	Routine care (includes care that should be offered to all women and babies)	**Complications care at first level** nclude initial management of complication and referral if necessary). Estimated proportion of target population (e.g. all pregnant women, all childbearing women, all newborns, etc.), who will require treatment is indicated in brackets).	**Complications care at back-up level**
Care during pregnancy	1.a. Assessment of mother and fetal well being, information and counselling on care and self care, including birth and emergency plan, breastfeeding and education on danger signs; family planning counselling and advice, recording and reporting. (part of ANC)	1.b. Additional care and counselling for women with special needs (adolescents, previous stillbirth, violence and other social problems)	
	2.a. Screening of hypertensive disorders of pregnancy (part of ANC)	2.b. Initial management of pre-eclampsia and eclampsia	2.c. Treatment of severe pre-eclampsia, eclampsia (3% of all women during pregnancy, birth and postpartum period).
	3.a. Prevention (iron supplementation) and screening for anaemia (part of ANC)	3.b. Treatment of mild to moderate anaemia (Hb:7-11g/dl)	3.c. Treatment of severe anaemia (3-5% of all women during pregnancy, birth, postpartum)
	4.a. Diagnosis of bleeding during pregnancy (part of ANC)	4.b. MVA for threatened or incomplete abortion (10-15%) and first line management of bleeding during pregnancy (e.g., ectopic pregnancy <0.5%, placenta praevia and abruption placenta (1%))	4.c. Treatment of bleeding in pregnancy (treatment of post abortion complications 0.05%, laparotomy 0.03% and c-section 0.5%
	5.a. Screening for maternal syphilis (part of ANC),	5.b. Presumptive treatment of syphilis (1-10% of all pregnant women)	
	6.a. STI/RTI diagnosis (Candida vaginitis, gonorrhoea, Chlamydia, bacterial vaginosis and trichomoniasis), (part of ANC).	6.b. STI/RTI management (Candida vaginitis, gonorrhoea, Chlamydia, bacterial vaginosis and trichomoniasis), (5-10% of all pregnant women)	
	7.a. Tetanus toxoid immunization (part of ANC)		
	8.a. Screening for urinary tract infection	8.b. Antibiotic treatment for lower urinary tract infection (4-7% of all pregnant women)	8.c. Treatment of acute pyelonephritis (2% of all pregnant women)
	9.a. Diagnosis of malpresentation (part of ANC)		9.c.External Cephalic Version (ECV), (4% of all pregnant women)
	10.a. Voluntarily Counselling and Testing (VCT) for HIV (part of ANC)	10.b. Counselling, support and treatment of opportunistic infections among HIV-positive pregnant women with ARV (1-40% of all pregnant women)	10.c. Treatment of opportunistic infections in HIV-positive women with ARV and provision of ARV for PMTCT (1-5% of all pregnant women)
Endemic areas	11.a. Antimalarial Intermittent preventive treatment (IPT) and insecticide treated nets (ITNs) (part of ANC)	11.b. Treatment of uncomplicated malaria (5-10% of all pregnant, birthing and postpartum)	11.c. Treatment of complicated malaria (less than 0.5% of all pregnant, birthing and postpartum women)
Endemic areas	12.a. Systematic treatment of hookworm infestation (100% of all pregnant women in endemic areas)		

	First-level MNH care (services provided close to clients)		Back-up care at sec. health-care level
Situational	13.a. Abortion care (where abortion is legal) (1-10%)		
Care of the mother and the newborn-baby during birth and the first 1-2 hours after birth	14.a. Routine care during labour, birth and the immediate post-partum period, which includes: care and social support during childbirth; regular monitoring for detection of complication and recording (including use of partograph); prevention and control of infection; and active management of third stage of labour.	14.b. Episiotomy (10-15% of all birthing women), Repair of vaginal / perineal tears (10% of all birthing women)	
	15.a. Detection of prolonged and obstructed labour	Initial management and referral of prolonged and obstructed labour and fetal distress (10-15%), Vacuum extraction (3% of all birthing women)	Breech delivery; Vacuum extraction; forceps; c-section (10-15% of all birthing women)
	16.a. Diagnosis of pre-labour rupture of membrane (PROM)	16.b. Initial management and referral of pre-labour rupture of membranes (PROM)	16.c. Management of pre-labour rupture of membranes (PROM) (5-7%)
	17.a. Detection of bleeding	17.b. Initial management of bleeding	17.c. Management of severe bleeding (5%)
	18.a. Identification of newborn breathing problems	18.b. Resuscitation, monitoring of breathing and pre-referral treatment of severe cases (4%)	18.c. Management of respiratory distress (2-4%)
	19.a. Identification of newborn hypothermia	19.b. Re-warm baby and pre-referral care of severe cases	19.c Management of severe hypothermia (2%)
Endemic areas	20.a. Prevent mother to child transmission of HIV (PMTCT) - and providing guidance and support with replacement feeding).	20.b. Administering of ARV	20.c. PMTCT including administering of ARV
Care of the mother from 1-2 hours after birth until discharge (24-48 hours at least)	21.a. Prevention (iron and folate supplementation) and detection of anaemia	21.b. Initial management of anaemia (40% of all women during pregnancy, birth and postpartum)	21.c. Management of severe anaemia (including blood transfusion) (3-5%)
	22.a. Prevention and control of infections	22.b. Initial management of sepsis (mastitis (5%), perineal (1%), lower urinary tract infection (4%)	22.c. Management of puerperal sepsis (5%)
	23.a. Identification of hypertensive disorders	23.b. Initial management of pre-eclampsia / eclampsia and pre-referral care (<1%)	23.c. Management of severe pre-eclampsia / eclampsia (<0.5%)
	24.a. Family Planning and decision-making on birth spacing	24.b. IUD insertion (3% of all birthing women)	24.c. Female sterilization (5-15%)
Newborn care from 1-2 hours after birth until discharge (24-48 hours at least)	25.a. Routine care of the newborn: Assessment of wellbeing, detection of complications, cord care, eye prophylaxis; advising mother on breastfeeding and newborn care, post-natal care visits, and danger signs.	25.b. Additional care if preterm, or birth weight less than 2500 or twin (additional care can include: special support for breastfeeding, additional warmth, ensure hygiene, monitor more often). Kangaroo Mother Care (5-10%)	
	26.a. Breastfeeding support and guidance	26.b. Additional assistance to mother to express breast milk or provide/advice on alternative feeding methods in case of feeding problems (1-40%)	26.c. Alternative feeding methods if baby is unable to feed (5-10%)
	27.a. Preventions and control of infections	27.b. Treatment of local infections (cord, skin, eye, thrush) and pre-referral care of severe infections (4%)	27.c. Management of neonatal sepsis (4% all baby)
	28.a. Immunization of baby with BCG		
	29.a. Immunization of baby - OPV-0		

	First-level MNH care (services provided close to clients)		Back-up care at sec. health-care level
	30.a. Immunization of baby - Hepatitis B (HB-1)		
			31.c. Management of neonatal tetanus (0.1%)
			32.c. Management of severe jaundice (5%)
	33.a. Verification of RPR status	33.b. Presumptive single dose of penicillin treatment in asymptomatic baby of RPR positive mother, treat/counsel partner (1-10%)	33.c. Treatment of congenital syphilis, 10 days (1%)
	34.a. Identification of babies at risk of infection (in case of PROM> 18 hours or maternal fever)	34.b. Pre-referral treatment with antibiotics (5-10%)	34.c. Presumptive treatment of infection - 5 days (5-10%)
	35.a. Identification of babies at risk of TB	35.b. Prophylaxis with isonlazide, postpone BCG, follow-up	
	36.a. Screening for birth trauma	36.b. Management of mild birth trauma and pre-referral care for severe trauma.	36.c. Management of severe birth trauma
	37.a. Screening for malformations	37.b. Pre-referral care for severe malformation and provide advice to parents on mild malformations.	37.c. Management of correctable congenital malformations
Endemic areas	38.a. Advise mother to keep baby under treated net.	38.b. Detection and pre-referral care of neonatal malaria	38.c. Treatment of malaria (1%)
Post-partum care (mother) - discharge to 6 weeks after birth	39.a. Routine postpartum care, which includes general assessment of mother's wellbeing, information and counselling on nutrition, care and self care; detection of any danger signs; monitoring and recording.	39.b. Mild postpartum depression management (10%)	39.c. Management of postpartum depression (2%)
	40.a. Prevention (iron and folate supplementation for 3 months after birth) and detection of anaemia	40.b. Initial management of mild and moderate anaemia	40.c. Management of severe anaemia, including blood transfusion (4% of p,b,p)
	41.a. Prevention and control of infections	41.b. Initial management of sepsis puerperal sepsis (5%), mastitis (5%), perineal infection (1%)	41.c. Management of severe puerperal sepsis 3%
	42.a. Family Planning and decision-making on birth spacing	42.b. IUD insertion (3% of all birthing women)	42.c. Sterilization (1-5%)
Endemic areas	43.a. Antimalarial intermittent preventive treatment (IPT) and insecticide treated nets (ITNs)	43.b. Treatment of uncomplicated malaria (5-10% of all women during pregnancy, birth and postpartum)	43.c. Treatment of complicated malaria (<0.5%)
Post natal care (baby), discharge to 4 weeks after birth	44.a. Routine neonatal care of the newborn: Assessment of wellbeing of the newborn and breastfeeding, regular monitoring for detection of complication, advising mother on breastfeeding, newborn care and danger signs.	44.b. Additional follow-up for low birth weight and high risk babies (replacement feeding, isoniazide prophylaxis, orphans, etc.)	44.c. Management of neonatal sepsis and other infections, detection and management of not lethal malformations, care of very low birth weight infants; care of newborns with failure to thrive (5-10%)

Annex 2: Special notes

Special note for units and biomaterials used for medical devices
Special note on packaging and labelling
Special note on injection safety
Special note on health-care waste management
Special note on surgical sutures
Special note on standard precautions for health workers
Special note on wearing protective equipment
Special note on textiles used for linen and clothing
Special note on sterilization of medical devices
Special note on surgical instruments, stainless steel

Special note for units and biomaterials used for medical devices

Units

The different units (symbols) used to express external diameter in medical devices are listed below:

Charrière = Ch, CH

Synonym: French gauge
Definition: Unit that expresses the external diameter in 1/3mm
CH 1 = 1/3 mm
Field of use: Tubes and drains
e.g.: CH 6 = 2mm or CH4 = 1.33mm

French gauge = F or FG

Synonym: French size, Charrière
Definition: Unit that expresses the external diameter in 1/3mm
1 FG = 1 CH = 1/3mm
Field of use: Exploratory catheters, tubes and drains.

Note: Some manufacturers offer catheters in Inches
e.g.: 5 FG = CH 5 = 1.66mm = 0.066 INCH

Gauge = G, Ga, Gg, g

Synonym: British standard gauge
Definition: Unit which expresses the external diameter of the product, in a range, from 8 to30, corresponding respectively: 4 to 0.3mm
Field of use: Short catheters, needles, scalp veins.

The higher the gauge, the smaller the external diameter. The gauge gives the external diameter, but does not take into account the thickness of the wall, so it will not indicate the internal diameter.
e.g.: 22G = 0.7 to 0.9mm - 18G = 1.1 to 1.3mm.

Note: the gauge/mm correspondence may vary, due to figures being rounded off in conversion from inches to mm.

Inch = In or ''

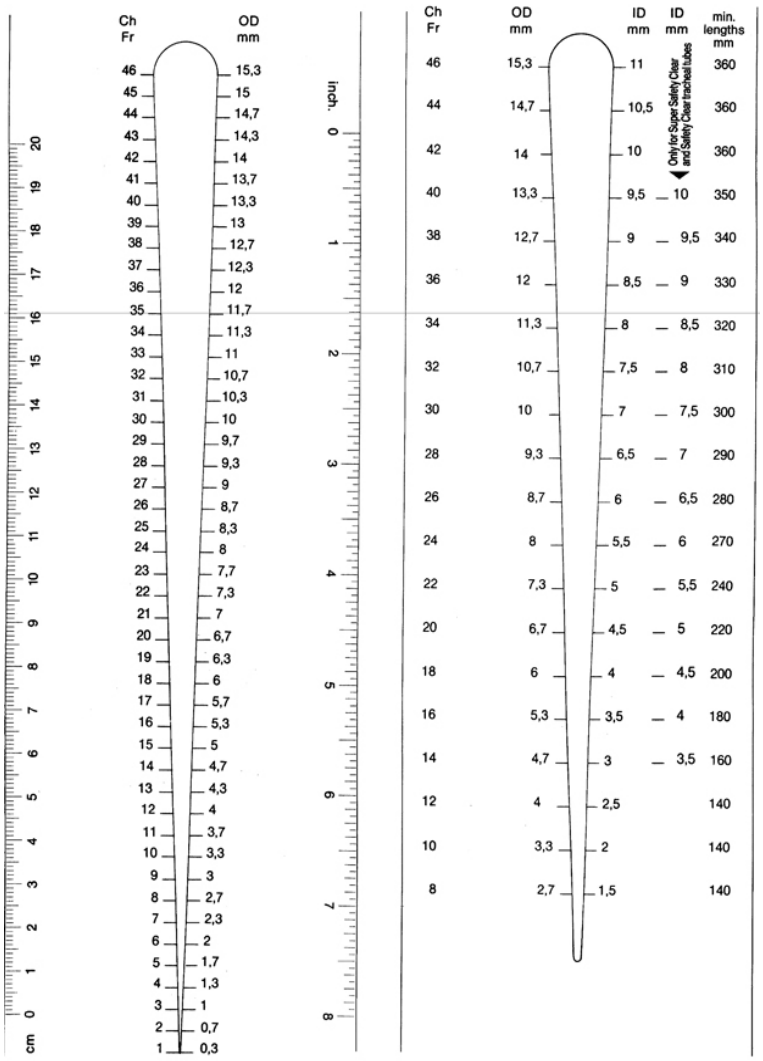
Synonym: In French « pouce »
Definition: Unit used to express the external diameter of guides for catheters
1 in = 1 inch = 25.4mm
1 mm = 0.04 in = 0.04''
Field of use: Guides for catheters.

Table of correspondence Gauge/mm and normalized colours for hypodermic needles (EN-ISO 6009, Hypodermic needles for single use - Colour coding for identification)

Dimension in gauge	Nominal ext. Ø in mm	Colour code
29 G	0.3 mm	-
27 G	0.4 mm	Grey
26 G	0.45 mm	Brown
25 G	0.5 mm	Orange
23 G	0.6 mm	Blue
22 G	0.7 mm	Black
21 G	0.8 mm	Dark green
20 G	0.9 mm	Yellow
19 G	1.0 mm	Cream
18 G	1.2 mm	Pink
17 G	1.5 mm	Red-violet
16 G	1.6 mm	White
15 G	1.8 mm	Grey-blue
14 G	2.1 mm	Light green
13 G	2.4 mm	-

Correspondence Charrière / mm

Catheters and drains **Endotracheal tubes**



NB: OD = Outer Ø, ID = Inner Ø

Biomaterials

The biomaterials used in the field of medical devices consumables are very disparate, covering all plastic substances intended for implanting in the human body for a fairly extended period. They are subject to biocompatibility and non-toxicity criteria.

Polymers

The selection of polymers used in the manufacture of medical devices consumables is based on criteria for use, consumption, product design (in particular, after sterilizing treatment), fabrication and industrial assembly.

Glossary of biomaterials used for medical devices materials

Polyolefine
HDPE: high density polyethylene
LDPE: low density polyethylene
PP: polypropylene

Polyvinyl
PVC: polyvinyl chloride
EVA: (polyethylene/vinyl acetate

Polystyrene
PS: polystyrene
ABS: acrylonitrile butadiene styrene

Polyacrylic
PMMA: polymethyl methacrylic

Polyamide
PA6
PA6/6 6.10
PA11

Cellulose
CA: cellulose acetate
CP: cellulose propionate
CAB: cellulose acetobutyrate

Linear polyester
Polydioxanone
PET: polyethylene terephthalate
PC: polycarbonate

Polyether
POM: polyacetal

Polyfluorethane
PTFE: polyetraflurethylene
PEF and FEP: polyethylene/propylene perfluorate

Polyurethane
PUR

Silicone
SI: silicone elastomer

Latex
Natural Rubber
Molded Rubber (obtained by coagulation of latex)
Sheet Rubber (type of natural rubber)

Non-woven (celluloid)
PE
PP
PA

Polyglycol

Characteristics sought / Most appropriate materials

- ***Flexibility:*** Silicone, Flexible PVC, PUR Thermoplastic PUR, LDPE
- ***Transparency:*** PMMA, PS, Celluloid, PP, PVC, PC, Silicone
- ***Permeability:*** Cellulose, LDPE, Silicone
- ***Impermeability:*** PVC, PET, PA,
- ***Mechanical strength:*** PA, POM, PET, ABS
- ***Shock resistance:*** PA, PC, PUR
- ***Low coefficient of friction:*** PFE, PA, POM, LDPE
- ***High temperature sterilization:*** PFE, Silicone, PA, PET, PC, PP
- ***High frequency welding:*** Flexible PVC
- ***Low price:*** LDPE, PP, HDPE

Steam sterilization of biomaterials (Autoclave)

The following table should be used for guidance only.

- ***Molded rubber:*** Satisfactory
- ***Latex:*** Satisfactory
- ***Sheet rubber:*** Satisfactory (not recommended for articles with balloon)

- ***Silicone:*** Satisfactory
- ***EVA:*** To be avoided
- ***PVC:*** Not recommended
- ***Red vinyl:*** Satisfactory
- ***Polyethylene:*** To be avoided
- ***Polypropylene:*** Satisfactory
- ***Polycarbonate:*** Satisfactory
- ***Polyurethane:*** To be avoided

Note: manufacturer's recommendations should always be followed.

Special note on packaging and labelling

Packaging

Any medical device must be supplied in a packaging.

Primary packaging, sterile or non-sterile as appropriate

Packaging in direct contact with the product, intended to protect one or more items, and if needed, to keep it (them) sterile until use.
EXAMPLES: sachet, plastic box, peel-off sachet (recommended for sterile items since the transparent film allows clear identification of the content).

For sterile medical devices: if the primary packaging has deteriorated (cracks, moulds etc.) the item can no longer be considered sterile. Check the integrity of each unit before use.

Secondary packaging

Packaging which constitutes the unit of sale or the unit of use, intended to protect the primary packaging of one or more items until use.
EXAMPLES: cardboard, rigid wrapping.

Tertiary packaging

Extra packaging intended to protect one or more wrapped items during transport and storage.

Labelling

Product labelling shall meet the essential requirements describe in GHTF document SG1- N043R3: Labelling for Medical Devices (including In Vitro Diagnostic Devices)

Labelling on the primary packaging

► The name or trademark of the manufacturer and/or the supplier	
► The article reference of the manufacturer and/or the supplier	
► The details needed to identify the device, ideally in English and in French (designation, description, composition as appropriate) EXAMPLE: The packaging of a surgical instrument must bear its designation and its nominal dimension in cm (= overall dimension or dimension of the active part, e.g. the blade)	
► The batch number prefixed by the word "LOT" or equivalent harmonized symbol, or the serial number prefixed by "SN"	
► For items with limited shelf live, the expiry date using the words “use before (month)/(year) or prefixed by "EXP" or equivalent harmonized symbol (month)/(year)	
► For items without expiry date, the date of manufacture (year) prefixed by the harmonized symbol, unless this information is already incorporated into the batch number or the serial number	
► For single use items, the words "DO NOT RE-USE" or "FOR SINGLE USE" or equivalent harmonized symbol	
► For sterile items, the word "STERILE" or equivalent harmonized symbol, plus a warning which advises to "check the integrity of the sterile packaging before use"	

Labelling on the secondary packaging:

The same labelling as on the primary packaging, and in addition:

► Any special storage and/or handling conditions	
► The instructions for use, ideally in English, French and Spanish, or the harmonized symbol which indicates that the item is supplied with a separate instruction leaflet.	

Expiration of medical devices with limited shelf-life

Sterile medical devices (example: injection supplies)

A sterile item with an expiry date that has passed can no longer be regarded as sterile and must be eliminated. If the expiry date only mentions the month and the year, it is the beginning of the month that must be considered the use-by date. How the constituent materials of medical/surgical equipment will change over time can only be determined by

the manufacturer who knows their exact composition. Nevertheless, the expiry date cannot exceed 5 years from the date of sterilization. This period of validity only applies if transport and storage are carried out under good conditions (protection from heat, humidity and light) and for items which have their sterile primary packaging intact.

Non-sterile medical devices (example: adhesive tape)

An item which has passed its expiry date no longer has the properties required for its use and so it should not be used. The period of validity only applies if transport and storage are carried out under good conditions (protected from heat, humidity and light) and for items of which have their primary packaging intact.

Special note on injection safety

To avoid risks of transmission of bloodborne pathogens, always use one single-use sterile needle and one single-use sterile syringe per patient and per injection, and to reconstitute each unit of injectable medication.

According to WHO recommendations on injection safety and to ensure injection device security:

- Promote oral treatment and limit the number of injections to only those strictly necessary. Use oral rehydration to limit the use of drips.
- Use auto-disable syringes with attached needles for immunization activities.
- Single-use syringes with a reuse-prevention feature should be considered for therapeutic injections, mostly where local data indicate that unsafe practices are particularly common.
- Ensure adequate supply of injection devices. All injectable medications are supplied with matching quantities of single-use needles, syringes, appropriate diluents and safety boxes/sharp containers according to the bundle principle.
- Use single-dose vials rather than multi-dose vials. If multi-dose vials must be used, always pierce the septum with a sterile needle and avoid leaving a needle in place in the vial stopper.
- Practice safe and rational use of blood transfusions. "any transfusion which is not specifically indicated is specifically contra-indicated."
- Collect used needles and syringes in a sharps container according to waste segregation rules.

References

- WHO. *Aide memoire on injection safety.* Available at: http://www.who.int/injection_safety/about/country/en/AMENG.pdf
- WHO *Guiding principles to ensure injection device security.* 2003. Document no. WHO/BCT/03.12 Available at: http://www.who.int/injection_safety/WHOGuidPrinciplesInjEquipFinal.pdf
- WHO-UNICEF-UNFPA *Joint statement on the use of auto-disable syringes in immunization service*s. 1999. Document no. WHO/V&B/99.25.
- WHO. *Best infection control practices for intradermal, subcutaneous and intramuscular injections, 2004.* Document no. WHO/BCT/DCT/01.02. Available at: http://www.who.int/injection_safety/toolbox/en/LeafletBestPracticesPrinter.pdf]
- WHO. Aide memoire on blood safety. Available at: http://www.who.int/bloodsafety/transfusion_services/en/Blood_Safety_Eng.pdf

Special note on health-care waste management

Health-care waste is a by-product of health care that includes sharps, non-sharps, blood, body parts, chemicals, pharmaceuticals, medical devices and radioactive materials. In order to avoid possible transmissions of infections by health-care waste, proper health-care waste management should be implemented and promoted in all situations.

Health-care waste management includes the following steps:

1. Segregation of the various categories of waste;
2. Storage and collection;
3. Treatment and disposal.

1. Segregation

The four major categories of health-care waste recommended for organizing segregation and separate storage, collection and disposal are (WHO 2005b):

- ***sharps*** (needles, scalpels etc.), which may be infectious or not;
- ***non-sharps infectious waste*** (anatomical waste, pathological waste, dressings, used syringes, used single-use gloves);
- ***non-sharps non-infectious waste*** (paper, packaging etc.);
- ***hazardous waste*** (expired drugs, laboratory reagents, radioactive waste, insecticides etc.).

2. Storage and collection

Sharps should be placed immediately in safe sharps containers, which are regularly collected for disposal.

Non-sharps infectious waste containers (15-40l capacity, with lids) should be collected, emptied, cleaned, disinfected and replaced after each intervention (e.g. in an operating or maternity unit) or twice daily.

Non-sharps non-infectious waste (20-60l capacity) should be collected, emptied, cleaned and replaced daily; alternatively, plastic bags may be used inside the containers (MSF 2005).

For the above categories of waste, it is recommended that waste containers are a maximum of 5m from the point of waste generation, in 2 sets for each location, for a minimum 3 types of waste. At least one set of waste containers should be provided per 20 beds in a ward (MSF 2005).

Hazardous waste should be collected and stored in appropriate labelled containers placed in a secure location. Radioactive waste should be stored in containers that prevent dispersion, behind lead shielding (Prüss, Giroult and Rushbrook, eds. 1999).

3. Treatment and disposal

Sharps should be disposed of in a sharps pit (buried drum in small centres or emergency structures, concrete-lined sealed pit in other settings).

Non-sharps infectious *waste* should be buried in a pit fitted with a sealed cover and ventilation pipe, or high-temperature incinerated. Special arrangements may be needed for disposing of placentas, according to local custom.

Steam sterilization prior to disposal, if available, is a preferred option for specific infectious waste such as blood samples, plastic syringes and laboratory tests, prior to disposal, as this avoids environmental pollution from incineration (Prüss, Giroult and Rushbrook, eds. 1999). It is important to dedicate one specific autoclave for waste sterilization that is different from the one used for sterilization of medical devices within the laboratory. See Diaz & Savage 2003 for details of a range of processes for treating infectious wastes.

Non-sharps non-infectious waste should be buried in a pit, a landfill site or recycled. If space is limited, it should be incinerated. If this is not possible, it may be burned in a drum burner. In both cases, ashes and residues should be buried in a pit.

There are several kinds of ***hazardous waste*** and each requires specific treatment and disposal methods, which include encapsulation, sterilization, burial, incineration and long-term storage. Some wastes, such as pharmaceutical wastes, cannot be disposed of safely in low-cost settings and should be sent to a large centre for destruction or returned to the supplier. For guidance on treatment and disposal of hazardous wastes, see Prüss, Giroult and Rushbrook, eds. (1999). In all cases, national legislation should be followed.

Waste zone

The waste-disposal zone should be fenced off; it should have a water point, with facilities for wastewater disposal into a soakaway system or sewer; and it should be located at least 30m from groundwater sources. Where an incinerator is used, it should be located to allow effective operation with minimal local air pollution in the health centre, nearby housing and crops; and it should be large enough for extension if new pits or other facilities have to be built. A handwashing point with soap/detergent and disinfectant should be provided.

References

- WHO health-care waste web site. Available at: http://www.healthcarewaste.org/en/115_overview.html
- WHO. *Safe management of wastes from health-care activities.* 1999. Available at: http://www.healthcarewaste.org/en/documents.html?id=1
- WHO Policy Paper. *Health-care waste management.* 2004. Available at: http://www.who.int/water_sanitation_health/medicalwaste/en/hcwmpolicye.pdf
- WHO. *Aide memoire on health-care waste management*. Available at: http://www.who.int/injection_safety/toolbox/en/AM_HCWaste.pdf

Special note on surgical sutures

Type of thread

Absorbable sutures

All the threads proposed are made of synthetic materials of slow absorption type (about 21 days).

No catgut since its use is proscribed for the following reasons:

- The catgut is absorbed in a few days, sometimes in less than 48 hours, and can cause reactions of rejection or inflammation (it is absorbed through a complex mechanism of enzymatic digestion, while synthetic absorbable threads are absorbed by simple hydrolysis).
- The catgut involves a risk of contamination since it is made of bovine gut (BSE: bovine spongiform encephalopathy) or ovine gut (trembling of sheep).

Selection: Synthetic braided thread.

Non-absorbable sutures

Inert thread, monofilament, braided or twisted, made of nylon, polyester, polypropylene or polyethylene. Silk and linen have been abandoned in favour of synthetic threads, which bring fewer problems of inflammation or rejection.

Selection: Synthetic monofilament

Size of thread

The thread size denotes its gauge. Two systems are used for measuring this gauge:

- Decimal size, representing a tenth of the thread diameter, expressed as a DEC number in the label (DEC2 = thread with a diameter of 0.20 mm)
- USP size, which ranges from 10/0 to 4, expressed between brackets in the label (the more zeros in the number, the finer the thread).

Thread with needle

- Threads with needles have an average length of 75 cm. The needles are either of triangular section (to pass through the skin more easily), or of round section (less traumatic for the majority of tissues).
- Sutures which have to be threaded onto needles are more traumatic when passing through tissues, increasing the risk of accident; consequently they have to be avoided.

Type of needle

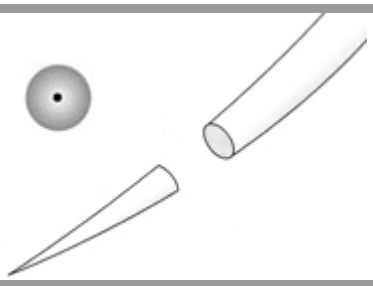
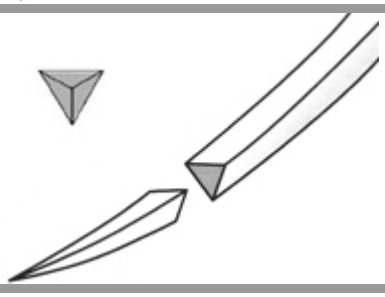
Suture needles are defined by their curvature (longitudinal shape), their body (cross section), their length and their diameter.

Needle shape

1. Curved needle, 1/2 circle (= half) (= 4/8) Deep sutures, stomatology, ENT, gynaecology…	
2. Curved needle, 3/8 circle General surgery, vascular sutures…	
3. Straight needle To be avoided (more dangerous than curved needles).	

Needle point

Round-bodied suture needles taper gradually to a point whereas triangular-bodied suture needles have cutting edges along three sides.

1. Round-bodied Sutures of soft tissues, mucous membranes and vessels.	
2. Triangular-bodied Sutures of muscles and skin.	

Special note on standard precautions for health workers

Universal precautions consist of protective barriers that break the chain of micro-organisms transmission. It applies to blood, all body fluids, secretions and excretions, non-intact skin and mucous membranes.

The protective barriers are simple procedures to protect health-care workers, patients, and attendants/visitors against the risk of infection:

- Handwashing after any direct contact with patients,
- Wearing of protective equipment for contact with body fluids, non-intact skin and mucous membranes,
- Safe handling of needles and sharps to prevent needlestick injuries, including preventing two-handed recapping of needles,
- Safe injection practices to prevent transmission of bloodborne pathogens to patients and health workers,
- Safe handling and disposal of medical related waste to prevent transmission of blood borne pathogens to the health-care providers, the waste handlers and the community at large,
- Safe handling of blood/body fluid specimens,
- Safe removal of blood/body fluid spills,
- Safe personal habits and working practices,
- Specific precautions in obstetric care, in operating theatre, in laboratory,
- Precautions for cleaning, laundry staff,
- Precautions for all health workers (vaccination against tetanus and hepatitis B).

Special note on wearing protective equipment

Health workers should always wear protective equipment when contact with blood or other body fluids is anticipated. Universal precautions include the following interventions:

Wearing examination gloves in case of:

- contact with blood, body fluids, mucous membranes or non- intact patient's skin
- contact with objects or surfaces soiled with blood or other body fluids
- for cervical examination during labour
- for post delivery care
- for care of newborn,
- presence of wounds on the hands
- checking and packing of medical devices before sterilization.

Wearing long-sleeved gloves (gynaecological/uterine gloves) where the hand and fore-arm need to be inserted into the vagina or uterus (e.g. manual removal of placenta, uterine revision…).

Wearing surgical gloves (sterile single use gloves) where rigorous asepsis is required.

Wearing cleaning gloves (reusable rubber gloves) in case of:

- handling and disposal of medical waste
- performing environmental cleaning activities

Wearing a mask and protective glasses and a gown (and sometimes a plastic apron) if blood or other body fluids might splash.

Wearing appropriate clean workwear covering or replacing "street clothes": dress, gown or tunic and trousers, with short sleeves to facilitate hand and wrist washing. Clothing items are made of easy-to wash and disinfect material (ideally cotton-polyester or cotton).

Wearing fluid resistant gown (or apron) and boots when performing procedures that may generate splashing or spraying (delivery, handling and cleaning of medical devices, handling and disposal of medical waste etc.).

Removing protective equipment as soon as the task is finished and discard in specific container according the type of equipment (see special note on health-care waste management).

Covering all cuts and abrasions with a waterproof dressing.

Disinfecting all reusable protective equipment (rubber gloves and apron, boots, protective glasses) with 0.5% active chlorine solution.

Changing at least twice a week gowns, tunics and trousers: (or more often if necessary): pre-disinfect with 0.1% active chlorine solution, wash and iron.

All surgical gown must pre-disinfect with 0.1% active chlorine solution, wash, iron and sterilize by autoclaving.

Washing hands with soap and water after removal of protective equipment.

Using manual or electrical mucous suction devices (never use the mouth tip system).

References

- WHO. *Aide memoire on health-care protection*. 2003. Document no. WHO/EHT/03.11. Available at : http://www.who.int/injection_safety/toolbox/docs/AM_HCW_Safety.pdf
- WHO. *Aide memoire on infection control.* Document no. WHO/EHT/04.15. Available at: http://www.who.int/injection_safety/AM_InfectionControl_Final.pdf
- Center for Disease Control and Prevention. *Guidelines for environmental infection control in health-care facilities*, 2003. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm
- WHO. *Prevention of hospital-acquired infections. A practical guide*. 2nd ed. 2002. Document no. WHO/CDS/CSR/EPH/2002.12. Available at: http://www.who.int/crs/resources/publications/drugresist/en/whocdscsreph200212.pdf

Special note on textiles used for linen and clothing

Single-use non-woven textiles

These satisfy less of a medical need but rather reduce the risks linked to contamination and nosocomial infections. They represent a large volume of contaminated waste which needs to be eliminated, preferably by incineration.

Non-woven textile used for single-use surgical linen:

- Composite material made of 3 layers:
  - absorbent non-woven material with orange peel structure,
  - non-porous, waterproof polyethylene,
  - absorbent cellulose voile to absorb the patient's sweat.

- Sometimes provided with adhesive area (fixing to the patient and antimicrobial barrier).

E.g.: surgical mask, surgical gown, surgical towel, surgical cap etc.

Three-layer fabric with outer plastic film layer used in case of SARS or haemorrhagic fever

- Material of three layers made of millions of high density polyethylene continuous fibres, heat-bonded
- Impervious to liquids and aerosols
- Permeable to air and to steam with anti-penetration barrier for fibres and particles < 1 μ
- Antistatic treated
- Heat-sealed seams

E.g.: Personal Protective Equipment (PPE), protective mask, protective gown, coverall etc..

Reusable woven textiles

Polyester/cotton

- Designation: 50% polyester-50% cotton fabric, heat-set
- Number of threads: warp: 24, weft: 22
- Metric count: warp: 28, weft: 28
- Weight per m^2: 175 g
- Washing: normal, withstands boiling and steam sterilization, resists to 0.5% chlorine

E.g.: surgical gown, surgical towel, medical staff clothing (tunic, trousers), patient tunic etc.

Cotton

- Designation: 100 % cotton cretonne fabric
- Number of threads: warp: 24, weft: 24

- Metric count: warp 28, weft: 28
- Weight per m²: 180 g
- Washing: normal, withstands boiling and steam sterilization, resists to 0.5% chlorine

E.g.: medical staff clothing (tunic, trousers), patient tunic etc.

Comparative results of the tests made on reusable woven textiles

- Dusting rates: Polyester/cotton gives off 50% less particles than cotton. Since it pollutes less, polyester/cotton is particularly recommended for surgical linen.
- Physical properties: Polyester/cotton shows the best physical properties. However, its resistance decreases in proportion to use and to the number of sterilization cycles.
- "Barrier" properties (bacteriological and physical resistance to liquids): New cotton can absorb the equivalent of its weight: high permeability, immediate bacterial passage. After the first sterilization cycle, polyester/cotton shows a high level of absorption, but the permeability is limited due to waterproofing treatments.

Special note on sterilization of medical devices

Processing of reusable medical devices must be done according the risk of infections (critical, semi-critical and non-critical items) and the heat resistant of the materials (thermoresistant or thermosensitive devices).

Classification of reusable medical device

1. ***Critical items*** are medical devices that are in contact with sterile parts of the body and items through which liquids circulate that go into the blood or sterile parts of the body (e.g.: surgical instruments, compresses, surgical drapes, syringes, urinary catheters, etc.). Critical items must be sterile at the time of use.

    - *Thermoresistant critical items* must be sterilized by steam autoclave between each patient and kept sterile until use. Thermoresistant materials (can be sterilized by steam sterilization): stainless steel, glass, latex, rubber, silicone, red vinyl, polypropylène, polycarbonate, linen, gauze.
    - *Thermosensitive critical items* are for single use only and must not be re-sterilized or re-used. Thermosensitive materials (do not withstand sterilization by steam autoclave): polyvinylchloride (PVC), ethylene vinyl acetate (EVA), polyurethane

2. ***Semi-critical items*** are items that are in contact with mucous membranes or superficially injured skin.

    - *Thermoresistant semi-critical items* must be sterilized by steam autoclave between each patient but need not necessarily be kept sterile until use.
    - *Thermosensitive semi-critical items* must be subjected to "high-level" disinfection between each patient.

3. ***Non-critical items*** are items that are in contact with intact skin and items that are not in contact with the patient.

    Non critical items must be regularly cleaned and disinfected but not necessarily between each patient, except if they have been soiled by blood or other biological fluids, or in case of infection requiring isolation (for example cholera and tuberculosis).

Steam sterilizaton method

Sterilization is the destruction of all microorganisms. Saturated steam sterilization is a physical sterilization method. It consists of exposure to steam saturated with water at 121°C for 30 minutes or 134°C for 13 minutes in an autoclave (134°C for 18 min for prions). Saturated steam sterilization is a reliable and easy to control sterilization method. Saturated steam sterilization represents the first choice for medical devices resistant to high temperatures and pressure.

High level disinfection

This consists of eliminating vegetative forms of bacteria and viruses (but not bacterial spores) by immersion of medical devices in a 0.1% active chlorine solution for 20 minutes). High disinfection concerns a restricted number of medical devices only, non-autoclavable (thermosensitive) and semi-critical which are likely to be reused. After "high" disinfection, medical devices cannot under any circumstances be considered as sterile.

Methods that are not recommended

Boiling

Boiling is a form of "high" disinfection and cannot be considered as sterilization. Boiling for 20 minutes (+ 5 minutes / 1000 m altitude) in a saucepan or other recipient eliminates vegetative forms of bacteria and viruses, including hepatitis and HIV viruses, but does not destroy bacterial spores.

Dry heat sterilizer

This method of sterilization does not give any advantage compared with the steam autoclave.
Dry heat sterilization is not always effective. Effectiveness is questionable on bacterial spores: for example, the destruction of the spores of B. anthracis requires 3 hours heating at 140º C. Dry heat is inefficient towards prions.

It is very difficult to meet the conditions of correct dry heat sterilization in precarious situations. This method of sterilization poses some practical problems, such as:

- the high temperature required deteriorates the materials;
- a perfect level surface is needed to use the sterilizer;
- its use for purposes other than sterilization is frequent and induces problems of hygiene;
- this method is only used for glass and stainless steel items.

References

- WHO. *Prevention of hospital-acquired infections. A practical guide.* 2nd ed. 2002. Document no. WHO/CDS/CSR/EPH/2002.12. Available at: http://www.who.int/crs/resources/publications/drugresist/en/whocdscsreph200212.pdf

Special note on surgical instruments, stainless steel

In order to guarantee good corrosion resistance, only steels which are completely stainless may be used for surgical instruments. Stainless steels are steels containing percentages of carbon, chromium, molybdenum, nickel, silicon, manganese and other elements, defined by the standard EN ISO 7153-1: Surgical instruments: Metal materials – Part 1: stainless steel.

There are two main types of stainless steel:

Martensitic stainless steels	Austenitic stainless steels
These are quenched, magnetic steels. They contain: CARBON => 0,1 to 1 % • Gives hardness and tensile strength • Lowers corrosion resistance CHROMIUM => 12 to 14 % • Essential alloying element • Gives corrosion resistance MOLYBDENUM => 0,2 to 1 % • Improves the cutting qualities • Gives corrosion and impact resistance • Cannot be used for pressure force instruments, as it makes them brittle SILICON => 0,5 to 1 % MANGANESE => 0,4 to 2 %	These are non-quenched, non-magnetic steels. They contain: CHROMIUM => 16 to 20 % • Essential alloying element • Gives corrosion resistance MOLYBDENUM => 2 to 3 % • Gives corrosion and impact resistance NICKEL => 8 to 12 % SILICON => 0,5 to 1 % MANGANESE => 0,4 to 2 %

Families of products

1. Pressure force instruments and springs => martensitic steel

- Haemostatic forceps
- Dissecting forceps
- Gripping forceps
- Surgical towel clamp
- Needle-holding forceps
- Threading forceps
- Clamping forceps

The steel used must be springy and highly impact resistant. Carbon gives them hardness, while chromium gives them corrosion resistance. The proportions must be very exact. Instruments made of these steels have to undergo a complex, rigorous heat treatment which allows the steel to be hardened; otherwise they will bend the first time they are used. Instruments made of these steels must be carefully polished; the quality of the polishing determines the corrosion resistance.

2. Instruments that cut by shearing => martensitic steel

- Scissors
- Curettes
- Raspatories
- Gouge shears
- Cutting forceps

The steel used has a higher percentage of carbon than for the pressure force instruments in order to increase hardness. The percentage of chromium is the same to give corrosion resistance, while incorporation of molybdenum makes up the balance and improves the cutting qualities.

3. Instruments that cut by percussion => martensitic steel

- Chisel shears
- Osteotomes
- Gouges

For the cutting part, the heat treatment and polishing are the same as for instruments that cut by shearing.
For the non-cutting part, the heat treatment and polishing are the same as for pressure force instruments.

4. Static function instruments => martensitic or austenitic steel

- Autostatic retractors
- Long-handled retractors
- Valves
- Speculums
- Dilators

5. Miscellaneous instruments=> austenitic steel

- Instrument box
- Obstetrical hook
- Manual drill etc.

Table of standard grades of steel for surgical instruments

Families of products	Type of steel	Composition of the steel					
		CARBON	CHROMIUM	MOLYBDENUM	NICKEL	SILICON	MANGANESE
1. Pressure force instruments & springs							
Haemostatic forceps	Martensitic	0.2 %	13 %			1 %	1 %
Dissecting forceps	Martensitic	0.2 %	13 %			1 %	1 %
Gripping forceps	Martensitic	0.2 %	13 %			1 %	1 %
Surgical towel clamps	Martensitic	0.2 %	13 %			1 %	1 %
Needle-holding forceps	Martensitic	0.2 %	13 %			1 %	1 %
Threading forceps	Martensitic	0.2 %	13 %			1 %	1 %
Clamping forceps	Martensitic	0.2 %	13 %			1 %	1 %
2. Instruments that cut by shearing							
Scissors	Martensitic	0.4 %	14 %			0.5 %	0.4 %
Curettes	Martensitic	0.2 %	13 %			1 %	1 %
Raspatories	Martensitic	0.2 %	13 %			1 %	1 %
Gouge shears	Martensitic	0.3 %	13 %			1 %	1 %
Cutting forceps	Martensitic	0.3 %	13 %			1 %	1 %
3. Instruments that cut by percussion							
Chisel shears	Martensitic	0.5–0.7 %	13–14 %	0.5-0.9 %		1 %	1 %
Osteotomes	Martensitic	0.5–0.7 %	13–14 %	0.5-0.9 %		1 %	1 %
Gouges	Martensitic	0.3 %	13 %			1 %	1 %
4. Static function instruments							
Autostatic retractors	Martensitic	0.3 %	13 %		8-10 %	1 %	2 %
Long-handled retractors	Austenitic		18 %		10-12 %	1 %	2 %
Valves	Austenitic		16–18 %	2-3 %	10-12 %	1 %	2 %
Speculums	Austenitic		16–18 %	2-3 %	8-10 %	1 %	2 %
Dilators	Austenitic		18 %			1 %	2 %
5. Miscellaneous instruments							
Instrument box etc.	Austenitic						